

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW MEXICO**

BOARD OF COUNTY COMMISSIONERS OF  
THE COUNTY OF COLFAX,

Plaintiff,

vs.

ALLERGAN PLC f/k/a ACTAVIS PLC,  
ALLERGAN FINANCE LLC f/k/a ACTAVIS,  
INC. f/k/a WATSON PHARMACEUTICALS,  
INC., ALLERGAN SALES, LLC, ALLERGAN  
USA, INC., WATSON LABORATORIES, INC.,  
WARNER CHILCOTT COMPANY, LLC,  
ACTAVIS PHARMA, INC. f/k/a WATSON  
PHARMA, INC., ACTAVIS SOUTH  
ATHLANTIC LLC, ACTAVIS ELIZABETH  
LLC, ACTAVIS MID ATLANTIC LLC,  
ACTAVIS TOTOWA LLC, ACTAVIS LLC,  
ACTAVIS KADIAN LLC, ACTAVIS  
LABORATORIES UT, INC. f/k/a WATSON  
LABORATORIES, INC.-SALT LAKE CITY,  
ACTAVIS LABORATORIES FL, INC. f/k/a  
WATSON LABORATORIES, INC.-FLORIDA,  
TEVA PHARMACEUTICALS USA, INC.,  
TEVA PHARMACEUTICAL INDUSTRIES  
LTD., CEPHALON, INC., JOHNSON &  
JOHNSON, JANSSEN PHARMACEUTICALS,  
INC., NORAMCO, INC., ORTHO-MCNEIL-  
JANSSEN PHARMACEUTICALS, INC.,  
JANSSEN PHARMACEUTICA, INC., ENDO  
HEALTH SOLUTIONS INC., ENDO  
PHARMACEUTICALS, INC., PAR  
PHARMACEUTICAL, INC., PAR  
PHARMACEUTICAL COMPANIES, INC. f/k/a  
PAR PHARMACEUTICAL HOLDINGS, INC.,  
ENDO INTERNATIONAL PLC, CARDINAL  
HEALTH, INC., McKESSON CORPORATION,  
AMERISOURCEBERGEN CORPORATION,  
ANDA, INC., CVS HEALTH CORPORATION;  
CVS INDIANA L.L.C.; CVS RX SERVICES,

Case No.: \_\_\_\_\_

**COMPLAINT**

**DEMAND FOR JURY TRIAL**

**This Complaint Relates to In Re National  
Prescription Opiate Litigation, MDL No. 2804**

**Case No. 17-md-2804**

**Judge Dan Aaron Polster  
N.D. Ohio (Eastern Division)**

INC.; CVS TN DISTRIBUTION, LLC; CVS PHARMACY, INC.; OMNICARE DISTRIBUTION CENTER LLC; OHIO CVS STORES, LLC; WALGREEN CO.; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN EASTERN CO., INC.; THE KROGER CO.; RITE AID CORP.; RITE AID HDQTRS. CORP.; ECKERD CORPORATION D/B/A RITE AID LIVERPOOL DISTRIBUTION CENTER; RITE AID OF OHIO, INC.; RITE AID OF MARYLAND, INC.; WALMART INC. F/K/A WAL-MART STORES, INC.; WAL-MART STORES EAST, LP; WSE MANAGEMENT, LLC; WSE INVESTMENT LLC; WAL- MART STORES EAST, INC.; KVK TECH, INC.; MYLAN PHARMACEUTICALS, INC.; WEST-WARD PHARMACEUTICALS CORP.; and ALBERTSON'S LLC,

Defendants.

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1. Board of County Commissioners of the County of Colfax (“Plaintiff” or Colfax County”) brings this action to prevent future harm and to redress past wrongs against

Defendants:

- Cephalon, Inc.; Teva Pharmaceuticals Industries, Ltd.; and Teva Pharmaceuticals USA, Inc.;
- Janssen Pharmaceuticals, Inc.; (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.); Johnson & Johnson; and Noramco, Inc.;
- Endo International plc; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; and Par Pharmaceutical Companies, Inc. (formerly known as Par Pharmaceutical Holdings, Inc.);
- Allergan PLC (formerly known as Actavis PLC); Allergan Finance LLC (formerly known as Actavis, Inc., formerly known as Watson Pharmaceuticals, Inc.); Watson Laboratories, Inc.; Actavis Pharma, Inc. (formerly known as Watson Pharma, Inc.); Actavis LLC; Allergan Sales, LLC; Allergan USA, Inc.; Warner Chilcott Company, LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Kadian LLC; Actavis Totowa LLC; Actavis South Atlantic LLC; Actavis Laboratories UT, Inc. (formerly known as Watson Laboratories, Inc. – Salt Lake City); and Actavis Laboratories FL, Inc. (formerly known as Wat Laboratories, Inc. – Florida);
- AmerisourceBergen Drug Corporation;
- Cardinal Health, Inc.;
- McKesson Corporation;
- And, Inc.;

- CVS Health Corporation; CVS Indiana L.L.C.; CVS Rx Services, Inc.; CVS TN Distribution, LLC; CVS Pharmacy, Inc.; Omnicare Distribution Center LLC; Ohio CVS Stores, LLC;
- Walgreen Co.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co., Inc.;
- Rite Aid Corp.; Rite Aid Hdqtrs. Corp.; Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center; Rite Aid of Ohio, Inc.; Rite Aid of Maryland, Inc.;
- Walmart Inc. (formerly known as Wal-Mart Stores, Inc.), Wal-Mart Stores East, LP; WSE Management, LLC; WSE Investment LLC; and Wal-Mart Stores East, Inc.
- The Kroger Co.;
- H. D. Smith, LLC d/b/a HD Smith, f/k/a H. D. Smith Wholesale Drug Co., H.D. Smith Holdings, LLC, H.D. Smith, LLC d/b/a HD Smith, f/k/a H.D. Smith Wholesale Drug Co., H.D. Smith Holdings, LLC, and H.D. Smith Holding Company; and
- KVK Tech, Inc.; Mylan Pharmaceuticals, Inc.; West-Ward Pharmaceuticals Corp.; and Albertson's LLC.

2. Plaintiff asserts claims against the pharmaceutical manufacturers of prescription opioid drugs that engaged in a massive false marketing campaign to drastically expand the market for such drugs and their own market share; claims against entities in the supply chain that reaped enormous financial rewards by refusing to monitor and restrict the improper distribution of those drugs; and claims to hold accountable the Chain Pharmacies that reaped enormous financial rewards by refusing to monitor and restrict the improper sale and distribution of opioids and abate the opioid epidemic in the County.

## **INTRODUCTION**

3. This case arises from the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.<sup>1</sup>

4. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. But few realize that this crisis arose from the opioid manufacturers’ deliberately deceptive marketing strategy to expand opioid use, together with the distributors’ equally deliberate efforts to evade or curtail restrictions on opioid distribution. Manufacturers and distributors alike acted without regard for the lives that would be trampled in pursuit of profit.

5. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015.<sup>2</sup> In the twelve months that ended in September 2017, opioid overdoses claimed 45,000 lives.

6. From 1999 through 2016, overdoses killed more than 350,000 Americans.<sup>3</sup> Over 200,000 of them, more than were killed in the Vietnam War, died from opioids prescribed by doctors to treat pain.<sup>4</sup> These opioids include brand-name prescription medications such as OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

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<sup>1</sup> Unless otherwise indicated, as used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

<sup>2</sup> *Overdose Death Rates*, NIH Nat’l Inst. on Drug Abuse, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (revised Sept. 2017).

<sup>3</sup> *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Aug. 30, 2017).

<sup>4</sup> *Prescription Opioid Overdose Data*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/data/overdose.html> (last updated Aug. 1, 2017).

7. Most of the overdoses from non-prescription opioids are also directly related to prescription opioids. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin, and the Centers for Disease Control and Prevention (“CDC”) identified addiction to prescription opioids as the strongest risk factor for heroin addiction.

8. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

9. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control and Prevention, “I don’t think we’ve ever seen anything like this. Certainly not in modern times.” On October 27, 2017, the President declared the opioid epidemic a public health emergency.

10. This suit takes aim at primary causes of the opioid crisis: (a) a marketing scheme involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase the demand for and sale of opioids and opioid prescriptions; and (b) a supply chain scheme, pursuant to which the various entities in the supply chain, including distributors and pharmacies, failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market.

11. On the demand side, the crisis was precipitated by the defendants who manufacture, sell, and market prescription opioid painkillers. Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Marketing Defendants relentlessly and methodically, but untruthfully, asserted that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of the long-term use of opioids.

12. The Marketing Defendants' goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

13. The Marketing Defendants' push to increase opioid sales worked. Through their publications and websites, endless stream of sales representatives, "education" programs, and other means, Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

14. Meanwhile, the Defendants made blockbuster profits. In 2012 alone, opioids generated \$8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately \$9.6 billion.

15. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies (together, “Defendants”), who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs, and fueling an illegal secondary market.

16. From the day they made the pills to the day those pills were consumed in our community, these manufacturers had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring doctors into prescribing their products by arguing, among other things, that no one should be in pain, the Marketing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Defendants’ profits soared as more and more people became dependent on opioids. Today, as many as 1 in 4 patients who receives prescription opioids long-term for chronic pain in a primary care setting struggles with addiction.

17. In 2014, almost two million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses

related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999.

18. As millions became addicted to opioids, “pill mills,” often styled as “pain clinics,” sprouted nationwide and prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

19. As a direct and foreseeable result of Defendants’ conduct, cities and counties across the nation, including Plaintiff, are now swept up in what the CDC has called a “public health epidemic” and what the U.S. Surgeon General has deemed an “urgent health crisis.”<sup>5</sup> The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

20. Thus, rather than compassionately helping patients in pain, this explosion in opioid use—and Defendants’ profits—has come at the expense of patients and Plaintiff has caused ongoing harm and damages to Plaintiff. As the CDC director concluded in 2014: “We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.”<sup>6</sup>

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<sup>5</sup> CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at <http://www.cdc.gov/give.washington/testimony/2014/t20140429.htm>; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at <http://turnthetidex.org>.

<sup>6</sup> *Id.*



21. Defendants' conduct in promoting opioid use, addiction, abuse, overdose, and death has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by Plaintiff and other governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others.

22. The burdens imposed on Plaintiff are not the normal or typical burdens of government programs and services. Rather, these are extraordinary costs and losses that are directly related to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

23. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis.

24. Within the next hour, six Americans will die from opioid overdoses; two babies will be born dependent on opioids and begin to go through withdrawal; and drug manufacturers will earn over \$2.7 million from the sale of opioids.

25. Colfax County has filed this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

### **JURISDICTION AND VENUE**

26. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiff's claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, raise a federal question. This Court has supplemental jurisdiction over the

Plaintiff's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

27. This Court has personal jurisdiction over all Defendants because the causes of action alleged in this Complaint arise out of each Defendants' transacting business in New Mexico, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, and because the Defendants regularly do or solicit business or engage in a persistent course of conduct or deriving substantial revenue from goods used or consumed or services rendered in this state. Defendants have purposefully directed their actions towards New Mexico and/or have the requisite minimum contacts with New Mexico to satisfy any statutory or constitutional requirements for personal jurisdiction.

28. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in this district. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in this district.

## **PARTIES**

### **I. PLAINTIFF**

29. Plaintiff Colfax County is a political subdivision of the State of New Mexico which may sue and plead in its own name.

30. Plaintiff is responsible for the public health, safety, and welfare of its citizens.

31. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity, and mortality has created a serious public health and safety crisis, and is a public nuisance, and the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance in Plaintiff's Communities.

32. The distribution and diversion of opioids into New Mexico and into Colfax County and surrounding areas (collectively, “Plaintiff’s Community”), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

33. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants’ conduct has exacted a financial burden for which the Plaintiff seeks relief. These damages have been suffered, and continue to be suffered directly, by the Plaintiff.

34. Plaintiff also seeks the means to abate the epidemic created by Defendants’ wrongful and/or unlawful conduct.

35. Plaintiff has standing to bring an action for the opioid epidemic nuisance created by Defendants.

36. Plaintiff has standing to recover damages incurred as a result of Defendants’ actions and omissions. Plaintiff has standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) (“persons” include entities which can hold legal title to property) and 18 U.S.C. § 1964 (“persons” have standing).

## **II. DEFENDANTS**

### **A. Marketing Defendants.**

37. At all relevant times, the Marketing Defendants, have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Marketing Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

# **1. Actavis Entities**

38. Defendant Allergan PLC (f/k/a Actavis plc) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc. and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, defendant Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc became wholly-owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.’s common shares was converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the “successor issuer” to Actavis, Inc. and Warner Chilcott plc. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc. AbbVie, Inc. (“AbbVie”) is a Delaware Corporation. On June 25, 2019, AbbVie announced it would acquire Allergan plc in a cash and stock transaction agreement valued at \$63 billion. As of the filing date of this complaint, the deal has yet to close. Plaintiffs herein reserve their rights to amend in AbbVie as a successor-in-interest to Allergan’s liability for the claims alleged in this complaint should that become necessary and appropriate.

39. The transaction that created Actavis plc converted each share of Actavis Inc.’s Class A common shares into one Actavis plc Ordinary Share. *See City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423, at \*7 (N.D. Ill. May 8, 2015). Actavis Inc. and Actavis plc had the same corporate headquarters both before and after the merger; Actavis plc

had the same website as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.’s officers in the same positions. *See id.* Actavis plc’s SEC filings explained that “[r]eferences throughout . . . to ‘we,’ ‘our,’ ‘us,’ the ‘Company’ or ‘Actavis’ refer” interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., or Actavis plc depending on the date. *See id.* (citations omitted).

40. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of Defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian’s label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

41. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application (“NDA”) holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications (“ANDAs”) for Norco. The Norco ANDAs are currently held by non-defendant Allergan Pharmaceuticals International Limited, which is incorporated in Ireland. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc.

42. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

43. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

44. Defendant Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly-owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

45. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is registered to do business with the California Secretary of State as a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

46. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was

sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

47. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of Kadian for Alpharma. Actavis Elizabeth LLC held the NDA for Kadian from 2008 to 2013. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

48. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

49. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

50. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis

Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

51. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on Kadian's label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

52. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

53. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to



Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

54. Each of these defendants and entities currently is or was previously owned by defendant Allergan plc, which uses or used them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates that manufacture, promote, distribute, and sell prescription opioids, are referred to as “Actavis.”

55. The Actavis Defendants manufacture or have manufactured the following drugs as well as generic versions of OxyCodone, Kadian, Duragesic, and Opana in the United States:

<b>Product Name</b>	<b>Chemical Name</b>	<b>Schedule</b>
Kadian	Morphine sulfate, extended release	Schedule II
Norco	Hydrocodone bitartate and acetaminophen	Schedule II

56. The Actavis Defendants made thousands of payments to physicians nationwide, including in and around Plaintiff’s geographical area, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

## **2. Cephalon Entities**

57. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”), an Israeli corporation (collectively “Teva”).

58. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

59. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, “Cephalon”) work together to manufacture, promote, distribute, and sell both brand name and generic versions of opioids including the following:

<b>Product Name</b>	<b>Chemical Name</b>	<b>Schedule</b>
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl buccal	Schedule II

60. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in and around Plaintiff’s geographical area, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids.

### **3. Janssen Entities**

61. Defendant Johnson & Johnson (“J&J”) is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

62. Defendant Janssen Pharmaceuticals, Inc. (“Janssen Pharmaceuticals”) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen’s products. Janssen Pharmaceuticals was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

63. Defendant Noramco, Inc. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

64. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMP”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

65. Defendant Janssen Pharmaceutica, Inc. (“Janssen Pharmaceutica”), now known as Janssen Pharmaceuticals, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

66. J&J, Janssen Pharmaceuticals, OMP, Janssen Pharmaceutica, Noramco, and their DEA registrant subsidiaries and affiliates (collectively, “Janssen”) are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, including in and around Plaintiff’s geographical area. Among the drugs Janssen manufactures or manufactured are the following:

<b>Product Name</b>	<b>Chemical Name</b>	<b>Schedule</b>
Duragesic	Fentanyl	Schedule II
Nucynta <sup>7</sup>	Tapentadol hydrochloride, immediate release	Schedule II
Nucynta ER	Tapentadol hydrochloride, extended release	Schedule II

67. Janssen made thousands of payments to physicians nationwide, including in and around Plaintiff’s geographical area, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

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<sup>7</sup> Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

68. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values, and principles. Janssen's employees are required to read, understand, and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is Johnson & Johnson's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

69. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

70. J&J made payments to thousands of physicians nationwide, including in and around Plaintiff's geographical area, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

#### **4. Endo Entities**

71. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

72. Defendant Endo Pharmaceuticals, Inc. (“EPI”) is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

73. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of defendant Par Pharmaceutical Companies, Inc. (f/k/a Par Pharmaceutical Holdings, Inc.). Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively as “Par Pharmaceutical.” Par Pharmaceutical was acquired by defendant Endo International plc (“Endo Int’l”) in September 2015 and is an operating company of Endo Int’l. EHS, EPI, Par Pharmaceutical, and Endo Int’l and their DEA registrant subsidiaries and affiliates (collectively, “Endo”) manufacture opioids sold nationally, including in and around Plaintiff’s geographical area.

74. Among the drugs Endo manufactures or manufactured are the following:

<b>Product Name</b>	<b>Chemical Name</b>	<b>Schedule</b>
Opana ER	Oxymorphone hydrochloride, extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Generic	Oxycodone	Schedule II
Generic	Oxymorphone	Schedule II
Generic	Hydromorphone	Schedule II
Generic	Hydrocodone	Schedule II

75. Endo made thousands of payments to physicians nationwide, including in and around Plaintiff’s geographical area, ostensibly for activities including participating on speakers’

bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

76. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of \$1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

77. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.<sup>8</sup>

78. At all relevant times, Endo has packaged, distributed, supplied, sold, and otherwise placed into the stream of commerce, both nationwide and in this jurisdiction, prescription opioids. Endo has also labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioids.

79. Further, Endo manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

80. Endo's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

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<sup>8</sup> FDA requests removal of OPANA ER for risks related to abuse. Available at: <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm> (accessed August 17, 2017).

81. Collectively, Actavis, Cephalon, Janssen, and Endo are referred to as “Marketing Defendants.”<sup>9</sup>

**5. Allegations Against Additional Manufacturing Defendants**

82. Defendant, KVK Tech, Inc. (“KVK”) is a Pennsylvania corporation with its principal place of business in Newton, Pennsylvania.

83. At all relevant times, KVK has packaged, distributed, supplied, sold, and otherwise placed into the stream of commerce, both nationwide and in this jurisdiction, opioid drugs. KVK has also labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs.

84. Further, KVK manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

85. Based on private ARCOS data made available to Plaintiff(s), drugs sold and manufactured by KVK represent a substantial market share in Plaintiff’s jurisdiction from at least 2006-2014.

86. KVK’s conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

87. Defendant, Mylan Pharmaceuticals, Inc. (“Mylan”), is a West Virginia corporation with its principal place of business in Canonsburg, Pennsylvania.

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<sup>9</sup> Together, Actavis, Cephalon, Janssen, and Endo are also sometimes referred to as “RICO Marketing Defendants.”

88. At all relevant times, Mylan has packaged, distributed, supplied, sold, and otherwise placed into the stream of commerce, both nationwide and in this jurisdiction, opioid drugs. Mylan has also labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs.

89. Further, Mylan manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

90. Based on private ARCOS data made available to Plaintiff(s), drugs sold and manufactured by Mylan represent a substantial market share in Plaintiff's jurisdiction from at least 2006-2014.

91. Mylan's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

92. Defendant West-Ward Pharmaceuticals Corp. ("West-Ward") is a Delaware corporation with its principal place of business located in Eatontown, New Jersey. West-Ward is the United States agent and subsidiary of Hikma Pharmaceuticals PLC ("Hikma"), a London-based global pharmaceutical company.

93. At all relevant times, West-Ward has packaged, distributed, supplied, sold, and otherwise placed into the stream of commerce, both nationwide and in this jurisdiction, opioid drugs. West-Ward also labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs.



94. Further, West-Ward manufactured and sold prescription opioids without fulfilling its legal duty to prevent diversion and report suspicious orders.

95. Based on private ARCOS data made available to Plaintiff(s), drugs sold and manufactured by West-Ward LLC represent a substantial market share in Plaintiff's jurisdiction from at least 2006-2014.

96. West-Ward's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

**B. Distributor & Dispenser Defendants**

97. The Distributor and Dispenser Defendants are defined below. At all relevant times, these Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor and Dispenser Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in “wholesale distribution,” as defined under state and federal law. The Dispenser Defendants are registered as “dispenser[s]” of opioids under state and federal law. Plaintiff alleges the unlawful conduct by these Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiff's community.

**1. Cardinal Health, Inc.**

98. Cardinal Health, Inc. (“Cardinal”) describes itself as a “global, integrated health care services and products company,” and is the fifteenth largest company by revenue in the U.S., with annual revenue of \$121 billion in 2016. Through its various DEA registrant subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio.

Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

**2. McKesson Corporation**

99. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016. McKesson, through its various DEA registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California until April 1, 2019, when it relocated to Las Colinas, Texas.

100. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan, and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [DEA] registered distributor."

**3. AmerisourceBergen Drug Corporation**

101. AmerisourceBergen Drug Corporation ("AmerisourceBergen"), through its various DEA registrants subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of \$147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

**4. Anda, Inc.**

102. Defendant Anda, Inc., (“Anda”) through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal offices located in Weston, Florida. In October 2016, defendant Teva acquired Anda from Allergan plc (i.e., defendant Actavis) for \$500 million in cash. At all times relevant to this complaint, Anda distributed prescription opioids throughout the United States, including in and around Plaintiff’s geographical area.

**5. CVS**

103. Defendant CVS Health Corporation (“CVS Health”) is a Delaware corporation with its principal place of business in Rhode Island. CVS Health, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and also operates retail stores, including in and around Plaintiff’s geographical area, that sell prescription medicines, including opioids.

104. Defendant CVS Indiana L.L.C. is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Defendant CVS Rx Services, Inc. is a New York corporation with its principal place of business in Chemung, NY. Defendant CVS TN Distribution, LLC is a Tennessee corporation with its principal place of business in Knoxville, TN.

105. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a wholly owned subsidiary of CVS Health. Defendant CVS Pharmacy, Inc. is both a DEA registered

“distributor”<sup>10</sup> and a DEA registered “dispenser”<sup>11</sup> of prescription opioids. Defendant Ohio CVS Stores, LLC is an Ohio corporation with its principal place of business in Woonsocket, Rhode Island.

106. Defendant Omnicare Distribution Center LLC is a Delaware corporation with its principal place of business in Ohio. Omnicare Distribution Center LLC, a CVS Health company, portrays itself as an industry leading long-term care pharmacy services provider focused on supporting community residents.

107. Defendants CVS Health Corporation, CVS Indiana L.L.C., CVS Rx Services, Inc., CVS TN Distribution, LLC, CVS Pharmacy, Inc., Omnicare Distribution Center LLC, and Ohio CVS Stores, LLC are collectively referred to as “CVS.” CVS conducts business as a licensed wholesale distributor and dispenser. At all times relevant to this Complaint, CVS distributed and/or dispensed prescription opioids throughout the United States, including in and around Plaintiff’s geographical area.

## **6. Walgreens**

108. Defendant Walgreen Co. acted as a retail pharmacy in the United States, until Walgreen Co. completed the acquisition of Alliance Boots, a British pharmacy giant, in 2014. After this acquisition, the company simply became Walgreens Boots Alliance, Inc. traded on NASDAQ under the symbol WBA.

109. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation that describes itself as the successor of Walgreen Co., an Illinois corporation. Both Walgreens Boots Alliance, Inc. and Walgreen Co. have their principal place of business in Illinois.

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<sup>10</sup> 21 U.S.C. §802(11) and §822(a)(1).

<sup>11</sup> 21 U.S.C. §802(10) and §822(a)(2).

110. Walgreen Co. is portrayed as a subsidiary of Walgreens Boots Alliance, Inc. and does business under the trade name Walgreens.

111. During the relevant time period, Walgreens self-distributed opioids and cocktail drugs to its own pharmacies from distribution centers which it owned and operated. At least between 2006 and 2014, Walgreens distributed opioids and cocktail drugs from its distribution centers, including those in Jupiter, Florida, Perrysburg, Ohio, and Mount Vernon, Illinois to Walgreens retail pharmacies located in and around Plaintiff's geographical area.

112. Defendant Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Deerfield, Illinois. Walgreen Eastern Co., Inc. is a subsidiary of Walgreens Boots Alliance, Inc.

113. Defendants Walgreens Boots Alliance, Inc., Walgreen Co., and Walgreen Eastern Co., Inc. are collectively referred to as "Walgreens."

114. Walgreens conducted business as a licensed wholesale distributor, as described above. Throughout the relevant time period, and as further alleged below, Walgreens entities also owned and operated pharmacies in and around Plaintiff's geographical area. At all times relevant to this Complaint, Walgreens distributed, dispensed, and/or otherwise sold prescription opioids throughout the United States, including in and around Plaintiff's geographical area.

115. The DEA distribution registrations for Walgreens's controlled substances distribution centers that distributed opioids and cocktail drugs into Plaintiff's geographical area were held by Walgreens Co. and/or Walgreens Eastern Co.

116. Walgreens Co. created, implemented, and had the power to enforce policies, practices, and training regarding distribution and sales in all Walgreens distribution and pharmacy sales operations.

117. The DEA dispensing registrations for Walgreens's pharmacies were held by Walgreens Co., which operated each pharmacy as a "d/b/a/" entity.

118. Expanding its chain pharmacy operations, Walgreens also acquired a number of former Rite Aid stores, including in and around Plaintiff's geographical area. Walgreens is liable as a successor for these stores' prior conduct, as well as for its own operations.

**7. Rite-Aid.**

119. Defendant Rite Aid Corporation is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania.

120. Defendant Rite Aid Hdqtrs. Corp. is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Defendant Rite Aid Hdqtrs. Corp. and Defendant Rite Aid Corporation, by and through their various DEA registered subsidiaries and affiliated entities, conduct business as licensed wholesale distributors and pharmacy operators.

121. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. is a subsidiary of Rite Aid Corporation and is itself a Maryland corporation with its principal office located in Camp Hill, Pennsylvania.

122. Defendant Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center is a subsidiary of Rite Aid Corporation and is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. and Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center distributed prescription opioids throughout the United States, including in and around Plaintiff's geographical area.

123. During the relevant time period, and as further alleged below, Rite Aid entities also owned and operated pharmacies in and around Plaintiff's geographical area through entities holding and operating retail pharmacies, on behalf of its parent company Rite Aid Corporation.

Orders of controlled substances came from Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. and Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center and other wholesalers. These controlled substances are distributed and dispensed according to practices and procedures established by Rite Aid Corporation and Rite Aid Headquarters Corporation.

124. Defendants Rite Aid Corporation, Rite Aid Hdqtrs. Corp., Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center, and Rite Aid of Ohio, Inc. are collectively referred to as “Rite Aid.”

125. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite Aid also operates retail stores, including in and around Plaintiff’s geographical area that sell prescription medicines, including opioids.

126. At all times relevant to this Complaint, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. distributed prescription opioids throughout the United States, including in and around Plaintiff’s geographical area.

## **8. Walmart**

127. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

128. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principal place of business in Arkansas.

129. Defendant WSE Management, LLC, is a Delaware limited liability company, and owns one percent of Wal-Mart Stores East, LP.

130. Defendant WSE Investment, LLC, is a Delaware limited liability company, and owns ninety-nine percent of Wal-Mart Stores East, LP.

131. The sole owner of both WSE Management, LLC and WSE Investment, LLC is Walmart-Stores East Inc., an Arkansas corporation.

132. The sole shareholder of Wal-Mart Stores East, Inc. is Walmart Inc., f/k/a Wal-Mart Stores, Inc.

133. Defendants Walmart Inc., f/k/a Wal-Mart Stores, Inc., Wal-Mart Stores East, LP, WSE Management, LLC, WSE Investment LLC, Wal-Mart Stores East, Inc. are collectively referred to as “Walmart.”

134. Walmart, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a registered wholesale distributor and as a pharmacy.

135. At all times relevant to this Complaint, Walmart distributed and sold prescription opioids throughout the United States, including in and around Plaintiff’s geographical area.

**9. The Kroger Co.**

136. Defendant The Kroger Co. (“Kroger”) is an Ohio corporation with headquarters in Cincinnati, OH. Kroger operates 2,268 pharmacies in the United States. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in and around Plaintiff’s geographical area.

**10. H.D. Smith**

137. Defendant H. D. Smith, LLC d/b/a HD Smith, f/k/a H. D. Smith Wholesale Drug Co., H.D. Smith Holdings, LLC, H.D. Smith Holding Company (“H. D. Smith”) is a Delaware corporation with its principal place of business in Springfield, Illinois. H. D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty



pharmaceuticals. At all times relevant to this Complaint, H. D. Smith distributed prescription opioids throughout the United States, including in and around Plaintiff's geographical area.

138. Collectively, Defendants CVS, Kroger, Rite Aid, Walgreens, and Wal-Mart are referred to as "Chain Pharmacies." Cardinal, McKesson, AmerisourceBergen, H.D. Smith, and the Chain Pharmacies are collectively referred to as the "Distributor Defendants."<sup>12</sup>

139. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships, and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale, and/or dispensing of opioids.

# **11. Allegations Against Additional Distributor Defendants**

140. Albertson's LLC is a Delaware limited liability company with its principal place of business in Boise, Idaho.

141. At all times relevant to this Complaint, Albertson's LLC, as a DEA registrant or through its DEA registrant subsidiaries and its affiliate entities, was in the business of distributing and redistributing prescription opioids through the United States, including in this jurisdiction. Albertson's was also authorized to conduct business in this jurisdiction.

142. Based on the private ARCOS data made available to Plaintiff(s), drugs sold and distributed by Albertson's LLC, represent a substantial market share in Plaintiff's jurisdiction from at least 2006-2014.

143. Albertson's conduct thus directly caused the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids across this country, including in this jurisdiction.

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<sup>12</sup> Together, Actavis, Cephalon, Janssen, Endo, Cardinal, McKesson, and AmerisourceBergen are sometimes referred to as "RICO Supply Chain Defendants."

**C. Agency and Authority**

144. Defendants include the above-referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships, and divisions to the extent that they are engaged in the manufacture, promotion, distribution sale and/or dispensing of opioids.

145. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

146. Plaintiff alleges that the corporate parents named as defendants in this Complaint are liable as a result of their own actions and obligations in distributing and selling opioids, and not solely because of their vicarious responsibility for the actions of their pharmacy stores.

**FACTUAL ALLEGATIONS**

**I. FACTS COMMON TO ALL CLAIMS**<sup>13</sup>

**A. Opioids and Their Effects**

147. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

148. The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids,

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<sup>13</sup> The allegations in this complaint are made upon information and belief. Plaintiff reserves the right to seek leave to amend or correct this Complaint based upon analysis of ARCOS data not yet available and upon further investigation and discovery.

three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine.

Early use of opium in Western medicine was with a tincture of opium and alcohol called

laudanum, which contains all of the opium alkaloids and is still available by prescription today.

Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

149. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."<sup>14</sup>

150. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

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<sup>14</sup> Nick Miroff, *From Teddy Roosevelt to Trump: How drug companies triggered an opioid crisis a century ago*, The Washington Post (Oct. 17, 2017), [https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm\\_term=.7832633fd7ca](https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca).

151. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

152. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration (“DEA”) since 1970.

153. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

154. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

155. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents (“MME”). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

156. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin’s twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

157. The wide variation in the MME strength of prescription opioids renders misleading any effort to capture “market share” by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation, even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

158. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Marketing Defendants’ promotion, with particularly lethal consequences.

159. The effects of opioids vary by duration. Long-acting opioids, such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. The Marketing Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or “breakthrough” pain. Short-acting opioids, such as Cephalon’s Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address “episodic pain” (also referred to as “breakthrough pain”) and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Insys’s Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer.

160. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the “high.” However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

161. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

162. As a leading pain specialist doctor put it, the widespread, long-term use of opioids “was a *de facto* experiment on the population of the United States. It wasn’t randomized, it wasn’t controlled, and no data was collected until they started gathering death statistics.”

## **B. The Resurgence of Opioid Use in the United States**

### **1. The Sackler Family Integrated Advertising and Medicine**

163. Given the history of opioid abuse in the U.S. and the medical profession’s resulting wariness, the commercial success of the Marketing Defendants’ prescription opioids would not have been possible without a fundamental shift in prescribers’ perception of the risks and benefits of long-term opioid use.

164. As it turned out, Purdue Pharma was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with a net worth of \$13 billion as

of 2016. All of the company's profits go to Sackler family trusts and entities.<sup>15</sup> Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

165. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company in 1952. It was Arthur Sackler who created the pharmaceutical advertising industry as we know it, laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

166. Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both print advertising in medical journals and promotion through physician “education” in the form of seminars and continuing medical education courses. He also understood the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his marketing firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.<sup>16</sup>

167. It was Arthur Sackler who, in the 1960s, made Valium into the first \$100-million drug, so popular it became known as “Mother’s Little Helper.” When Arthur’s client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called “psychic tension”—essentially

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<sup>15</sup> David Armstrong, *The man at the center of the secret OxyContin files*, Stat News (May 12, 2016), <https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/>.

<sup>16</sup> Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* (Rodale 2003) (hereinafter “Meier”), at 204.

stress—and pitched Valium as the solution.<sup>17</sup> The campaign, for which Arthur was compensated based on volume of pills sold,<sup>18</sup> was a remarkable success.

168. Arthur Sackler created not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which was distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like Marketing Defendants, who utilize it to target and tailor their sales pitches to individual physicians.

## **2. Purdue and the Development of OxyContin**

169. After the Sackler brothers acquired the Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue, which would have been a conflict of interest. Raymond Sackler became Purdue's head executive, while Mortimer Sackler ran Purdue's UK affiliate.

170. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard had grand ambitions for the company;

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<sup>17</sup> Meier, *supra* note 16, at 202; *see also One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), <http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids>.

<sup>18</sup> Meier, *supra* note 16.



according to a long-time Purdue sales representative, “Richard really wanted Purdue to be big—I mean *really* big.”<sup>19</sup> Richard believed Purdue should develop another use for its “Contin” timed-release system.

171. In 1990, Purdue’s vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what’s more, it was sometimes mistakenly called “oxycodine,” which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of “misbranding” in 2007, admitting that it was “well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine” and “did not want to do anything ‘to make physicians think that oxycodone was stronger or equal to morphine’ or to ‘take any steps . . . that would affect the unique position that OxyContin’” held among physicians.<sup>20</sup>

172. For Purdue and OxyContin to be “*really* big,” Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug’s uses beyond cancer pain and hospice care. A marketing memo sent to Purdue’s top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with

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<sup>19</sup> Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), <http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/>.

<sup>20</sup> Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), <http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/>.

OxyContin than with traditional immediate-release narcotics, sales would increase.<sup>21</sup> As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

173. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non-acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, “There are 50 million patients in this country who have chronic pain that’s not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that.”<sup>22</sup>

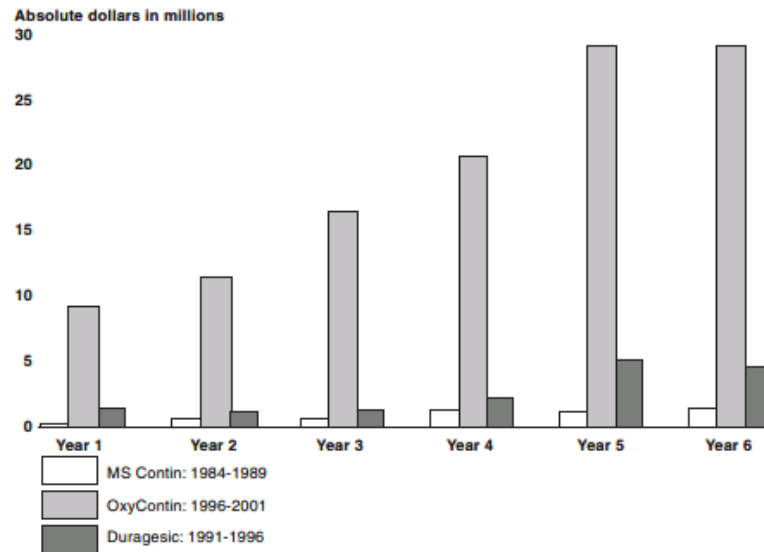
174. In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin’s sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin’s launch dwarfed Purdue’s spending on MS Contin or Defendant Janssen’s spending on Duragesic:<sup>23</sup>

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<sup>21</sup> Meier, *supra* note 16, at 269.

<sup>22</sup> *Id.*, at 156.

<sup>23</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters at 22 (Dec. 2003), <http://www.gao.gov/new.items/d04110.pdf>.

**Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales**

Source: DEA and IMS Health, Integrated Promotional Service Audit.

Note: Dollars are 2002 adjusted.

175. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

176. In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

177. Purdue has generated estimated sales of more than \$35 billion from opioids since 1996, raking in more than \$3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its 2006 sales of \$800 million.

178. One might imagine that Richard Sackler's ambitions have been realized. But in the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits.

Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

179. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue’s deadly legacy on a global stage. . . .

Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .

In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S.,

though now in countries with far fewer resources to devote to the fallout.<sup>24</sup>

180. Purdue’s recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused—only serves to underscore that Purdue’s actions have been knowing, intentional, and motivated by profits throughout this entire story.

### **3. Other Marketing Defendants Leapt at the Opioid Opportunity**

181. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other Marketing Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in greater detail in Section D below.

182. Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin’s active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved highly susceptible to abuse. Called “blues” after the light blue color of the 10 mg pills,

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<sup>24</sup> Letter to Dr. Margaret Chan, World Health Organization (May 3, 2017), [http://katherineclark.house.gov/\\_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf](http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf).

Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, “Drugs and Addict Lifestyle,” Numorphan was extremely popular among addicts for its quick and sustained effect.<sup>25</sup> Endo withdrew oral Numorphan from the market in 1979.<sup>26</sup>

183. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name, Opana.

184. The clinical trials submitted with Endo’s first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new “enriched enrollment” clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

185. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that this is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale

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<sup>25</sup> John Fauber and Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), <https://www.medpagetoday.com/psychiatry/addictions/51448>.

<sup>26</sup> *Id.*

due to the public health consequences of abuse.”<sup>27</sup> On July 6, 2017, Endo agreed to withdraw Opana ER from the market.<sup>28</sup>

186. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of Duragesic through, for example, advertisements proclaiming, “It’s not just for end stage cancer anymore!” This claim earned Janssen a warning letter from the FDA, for representing that Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.”<sup>29</sup>

187. Janssen also developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011.

188. By adding additional opioids or expanding the use of their existing opioid products, the other Marketing Defendants took advantage of the market created by Purdue’s aggressive promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than \$1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the \$1 billion mark in sales of Duragesic in 2009.

### **C. Defendants’ Conduct Created an Abatable Public Nuisance**

189. As alleged throughout this Complaint, Defendants’ conduct created a public health crisis and a public nuisance.

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<sup>27</sup> Press Release, U.S. Food & Drug Administration, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

<sup>28</sup> *Endo pulls opioid as U.S. seeks to tackle abuse epidemic*, Reuters (July 6, 2017, 9:59am), <https://www.reuters.com/article/us-endo-intl-opana-idUSKBN19R2II>.

<sup>29</sup> March 30, 2000 FDA letter to Janssen

190. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by, inter alia, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

191. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well positioned to do so. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. And, all companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist independent of any FDA or DEA regulation, to ensure that their products and practices meet both federal and state consumer protection laws and regulations. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

**D. The Marketing Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception and Increase Demand for Opioids**

192. In order to accomplish the fundamental shift in perception that was key to successfully marketing their opioids, the Marketing Defendants designed and implemented a sophisticated and deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Marketing Defendants turned to the marketing techniques first pioneered by



Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

193. The Marketing Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, had established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Marketing Defendants of these risks. The Marketing Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively exposed the known falsity of these Defendants’ misrepresentations.

194. The marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Marketing Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled (“Front Groups”), so-called industry “Key Opinion Leaders,” and Continuing Medical Education (“CME”) programs discussed subsequently below.

**1. The Marketing Defendants Promoted Multiple Falsehoods About Opioids**

195. The Marketing Defendants’ misrepresentations fall into the following nine categories:

- a. The risk of addiction from chronic opioid therapy is low.

- b. To the extent there is a risk of addiction, it can be easily identified and managed.
- c. Signs of addictive behavior are “pseudo addiction,” requiring more opioids.
- d. Opioid withdrawal can be avoided by tapering.
- e. Opioid doses can be increased without limit or greater risks.
- f. Long-term opioid use improves functioning.
- g. Alternative forms of pain relief pose greater risks than opioids.
- h. OxyContin provides twelve hours of pain relief.
- i. New formulations of certain opioids successfully deter abuse.

196. Each of these propositions was false. The Marketing Defendants knew these propositions were false, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

197. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant’s liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant’s conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant’s misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to

discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant.

**a. Falsehood #1: The risk of addiction from chronic opioid therapy is low**

198. Central to the Marketing Defendants’ promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by “legitimate” pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

199. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

200. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, “even at recommended dose,”<sup>30</sup> and the risk substantially increases with more than three months of use.<sup>31</sup> As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).<sup>32</sup>

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<sup>30</sup> FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013); *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm>.

<sup>31</sup> CDC Guideline at 21.

<sup>32</sup> *Id.* at 2.

**i. Purdue's misrepresentations regarding addiction risk**

201. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

202. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids.<sup>33</sup> They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients’ records.

**ADDICTION RARE IN PATIENTS TREATED  
WITH NARCOTICS**

*To the Editor:* Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients<sup>1</sup> who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,<sup>2</sup> Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER  
HERSHEL JICK, M.D.  
Boston Collaborative Drug  
Surveillance Program

Waltham, MA 02154      Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.  
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

<sup>33</sup> Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *N Engl J Med*. 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

203. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.<sup>34</sup>

204. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.<sup>35</sup> Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

205. Purdue specifically used the Porter and Jick letter in its 1998 promotional video “I got my life back,” in which Dr. Alan Spanos says, “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.”<sup>36</sup> Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)<sup>37</sup>

206. Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants’ misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph

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<sup>34</sup> Meier, *supra* note 16, at 174.

<sup>35</sup> J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New. Eng. J. Med. 123 (1980).

<sup>36</sup> Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyeI> (last visited Jan. 31, 2018) (emphasis added).

<sup>37</sup> Patrick R. Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017) (hereinafter, “Keefe, *Empire of Pain*”).

1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy . . .<sup>38</sup>

207. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”<sup>39</sup>

208. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, “The fear of addiction is exaggerated.”<sup>40</sup>

209. At a hearing before the House of Representatives’ Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized “legitimate” treatment, dismissing cases of overdose and death as something that would not befall “legitimate” patients: “Virtually all of these reports involve people who are

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<sup>38</sup> Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150>.

<sup>39</sup> *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

<sup>40</sup> Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), <http://documents.latimes.com/oxycontin-press-release-1996/>.

abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional.”<sup>41</sup>

210. Purdue spun this baseless “legitimate use” distinction out even further in a patient brochure about OxyContin, called “A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.” In response to the question “Aren’t opioid pain medications like OxyContin Tablets ‘addicting’?,” Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.<sup>42</sup>

211. Sales representatives marketed OxyContin as a product ““to start with and to stay with.””<sup>43</sup> Sales representatives also received training in overcoming doctors’ concerns about addiction with talking points they knew to be untrue about the drug’s abuse potential. One of Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s you prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!”<sup>44</sup>

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<sup>41</sup> *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

<sup>42</sup> *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

<sup>43</sup> Keefe, *Empire Of Pain*.

<sup>44</sup> Meier, *supra* note 16, at 102.

According to the memo, the target is physician resistance based on concern about addiction: “The physician wants pain relief for these patients without addicting them to an opioid.”<sup>45</sup>

212. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors’ objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that “it’s just too addictive.”<sup>46</sup> May and his coworkers were trained to “refocus” doctors on “legitimate” pain patients, and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers than need to be taken every four hours.

213. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

214. With regard to addiction, Purdue’s label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have “abuse potential” and that the “risk of abuse is increased in patients with a personal or family history of substance abuse.”

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<sup>45</sup> *Id.*

<sup>46</sup> David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), *The New Yorker* (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.



**ii. Endo’s misrepresentations regarding addiction risk**

215. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

216. Until April 2012, Endo’s website for Opana, *www.opana.com*, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

217. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER.

218. One of the Front Groups with which Endo worked most closely was the American Pain Foundation (“APF”), described more fully below. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control (“NIPC”) and its website *Painknowledge.com*, which claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”

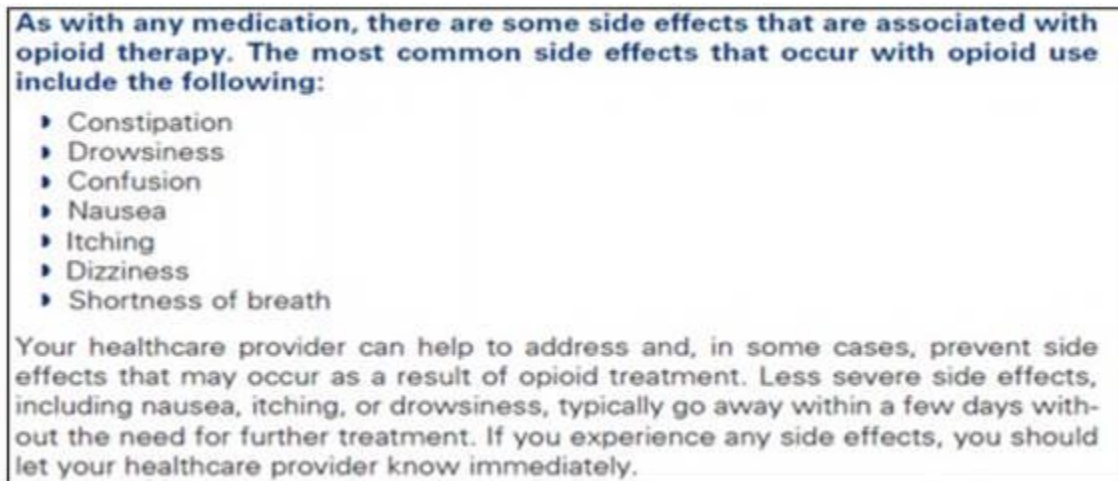
219. Another Endo website, *PainAction.com*, stated: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

220. A brochure available on *Painknowledge.com* titled “*Pain: Opioid Facts*,” Endo-sponsored NIPC stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” In numerous patient education pamphlets, Endo repeated this deceptive message.

- In a patient education pamphlet titled “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question—“What should I know about opioids and addiction?”—by focusing on explaining what addiction is (“a chronic brain disease”) and is not (“Taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.” This publication is still available online.

221. An Endo publication, *Living with Someone with Chronic Pain*, stated, “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”

222. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *Painknowledge.com*, omitted addiction from the “common risks” of opioids, as shown below:



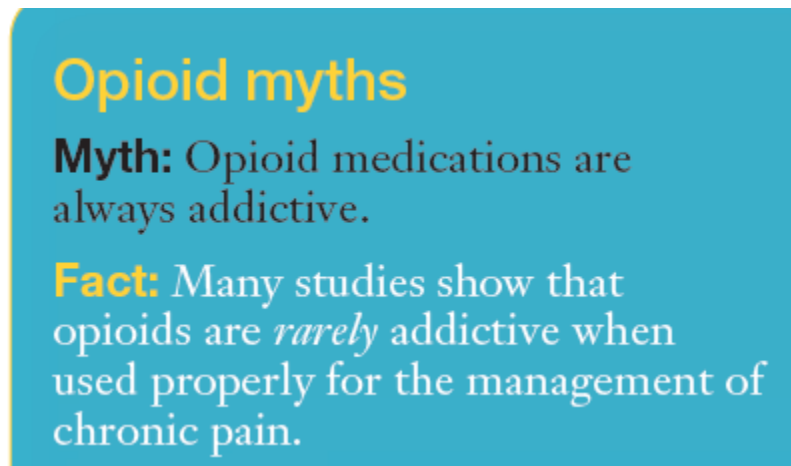
### iii. Janssen’s misrepresentations regarding addiction risk.

223. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials.

224. A Janssen unbranded website, *Let’s Talk Pain*, perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain which can be resolved with “effective pain management.”

225. A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”<sup>47</sup>

226. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” Until recently, this guide was still available online.



**iv. Cephalon’s misrepresentations regarding addiction risk.**

227. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient’s Guide*, which included claims that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.” Similarly, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain*

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<sup>47</sup> Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

(2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

228. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.<sup>48</sup>

**v. Actavis's misrepresentations regarding addiction risk.**

229. Doctors have a strong recollection of Kadian sales representatives' discussing the drug's low-abuse potential.

230. Actavis misrepresentations conveyed both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

**vi. Mallinckrodt's misrepresentations regarding addiction risk**

231. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of

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<sup>48</sup> Michael J. Brennan, et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, <http://www.medscape.org/viewarticle/449803> (last visited Oct. 10, 2017).

addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the “C.A.R.E.S. Alliance” it created and led.

232. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as “a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.” The “C.A.R.E.S. Alliance” itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

233. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.”
- “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- “**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he

doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain.”

- “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

234. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, “[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated” and cites to a report that concludes that “the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.”

235. Marketing Defendants’ suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who “doctor-shop”—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

**b. Falsehood #2: To the extent there is a risk of addiction, it can be easily identified and managed**

236. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify

patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

237. Purdue shared its *Partners Against Pain* “Pain Management Kit,” which contains several screening tools and catalogues of Purdue materials, which included these tools, with prescribers. Janssen, on its website [PrescribeResponsibly.com](http://PrescribeResponsibly.com), states that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors.<sup>49</sup> The website, which directly provides screening tools to prescribers for risk assessments,<sup>50</sup> includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.<sup>51</sup>

238. Purdue and Cephalon sponsored the APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed.”

239. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, a KOL discussed below, entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

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<sup>49</sup> Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction> (last modified July 2, 2015).

<sup>50</sup> <http://www.prescriberesponsibly.com/risk-assessment-resources> (last visited March 2, 2018).

<sup>51</sup> *Id.*

240. Purdue sponsored a 2011 CME program titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.”

241. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

242. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (“ORT”) created by Dr. Webster and linked to Janssen or (b) the *Screeener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts. The ORT was linked to by Endo-supported websites, as well.

243. There are three fundamental flaws in the Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that



patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

c. **Falsehood #3: Signs of addictive behavior are “pseudoaddiction,” requiring more opioids**

244. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term “pseudoaddiction,” which he characterized as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.”<sup>52</sup> In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from undertreatment of their pain.

245. In the materials and outreach they produced, sponsored, or controlled, Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

246. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards’ (“FSMB”) *Responsible Opioid Prescribing* (2007) written by Dr. Fishman and discussed in more detail below, which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of “pseudoaddiction.”

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<sup>52</sup> David E. Weissman and J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565>. (“Iatrogenic” describes a condition induced by medical treatment.)

247. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including “illicit drug use and deception” that it claimed was not evidence of true addiction but “pseudoaddiction” caused by untreated pain.

248. Even though its sales representatives promoted pseudoaddiction, Endo itself has repudiated the concept of pseudoaddiction. In finding that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the New York Attorney General, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”<sup>53</sup> Endo thereafter agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York.

249. Janssen sponsored, funded, and edited a website called *Let’s Talk Pain*, which in 2009 stated “pseudoaddiction . . . refers to patient behaviors that may occur when *pain is undertreated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until at least May 2012.

250. Janssen also currently runs a website, *Prescriberresponsibly.com*, which claims that concerns about opioid addiction are “overestimated,” and describes pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy

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<sup>53</sup> Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

being prescribed. Typically when the pain is treated appropriately the inappropriate behavior ceases.”<sup>54</sup>

251. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

**d. Falsehood #4: Opioid withdrawal can be avoided by tapering**

252. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients’ dose to avoid the adverse effects of withdrawal. Defendants fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

253. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient’s opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea,

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<sup>54</sup> *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids> (last visited Oct. 9, 2017).

headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

254. Purdue sponsored the American Pain Foundation's ("APF") *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

255. To this day, the Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

e. **Falsehood #5: Opioid doses can be increased without limit or greater risks**

256. In materials they produced, sponsored, or controlled, Marketing Defendants instructed prescribers that they could safely increase patients' dose to achieve pain relief. Each of the Marketing Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

257. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

258. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for dosing and ask, "if there are any reservations in using a dose of 240mg-320mg of OxyContin."<sup>55</sup>

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<sup>55</sup> *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>.

259. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. “Doctor, what is the highest dose of OxyContin you have ever prescribed?” “20mg Q12h.” “Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?” “Okay.” “Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?” “I don’t know, maybe.” “Doctor, but you do agree that you would at least Rx the 40mg dose, right?” “Yes.”

The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

260. These misrepresentations were particularly dangerous. As noted above, opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

261. In its 2010 Risk Evaluation and Mitigation Strategy (“REMS”) for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that “dose adjustments may be made every 1-2 days”; “it is most appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”<sup>56</sup>

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<sup>56</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., <https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf> (last modified Nov. 2010).

262. Endo sponsored a website, *Painknowledge.com*, which claimed that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

263. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased . . . You won’t ‘run out’ of pain relief.”

264. Purdue and Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have “no ceiling dose” and therefore are safer than NSAIDs.

265. Marketing Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.” A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

**f. Falsehood #6: Long-term opioid use improves functioning**

266. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids as capable of improving patients’ function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

267. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine...We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the “life uninterrupted” message in promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less about their pain.” This is a competitive advantage based on our inability to make any quality of life claims.<sup>57</sup>

268. Despite its acknowledgment that “[w]e do not have such data to support OxyContin promotion,” Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users’ function. This ad earned a warning letter from the FDA, which admonished, “It is particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”<sup>58</sup>

269. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”

270. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a

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<sup>57</sup> Meier, *supra* note 16, at 281.

<sup>58</sup> Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, Wall Street Journal (Jan. 23, 2003, 12:01am), <https://www.wsj.com/articles/SB1043259665976915824>.

“writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

271. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

272. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.

273. In addition, Janssen’s *Let’s Talk Pain*, website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

274. The APF’s *Treatment Options: A Guide for People Living with Pain* (2007), sponsored by Purdue and Cephalon, counseled patients that opioids “give [pain patients] a quality of life we deserve.” The guide was available online until APF shut its doors in May 2012.

275. Endo’s NIPC website *Painknowledge.com* claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily



living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” In addition to “improved function,” the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement.

276. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

277. Mallinckrodt’s website, in a section on responsible use of opioids, claims that “[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society.”<sup>59</sup>

278. The Marketing Defendants’ claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and quality of life.<sup>60</sup> Based upon a review of the existing scientific evidence,

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<sup>59</sup> Mallinckrodt Pharmaceuticals, Responsible Use, <http://www.mallinckrodt.com/corporate-responsibility/responsible-use>

<sup>60</sup> The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis’ opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, *footnote continued on next page*

the CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use.”<sup>61</sup>

279. Consistent with the CDC’s findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients’ health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had “consistently poor results,” and “several studies have showed that opioids for chronic pain may actually worsen pain and functioning . . .”<sup>62</sup> along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

280. On the contrary, the available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”<sup>63</sup> According to the CDC, “for the vast majority of patients, the known, serious, and

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President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that “patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”). The FDA’s warning letters were available to Defendants on the FDA website.

<sup>61</sup> CDC Guideline at 20.

<sup>62</sup> Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, New England Journal of Medicine, at 1503 (Apr. 21, 2016)

<sup>63</sup> CDC Guideline at 2, 18.

too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”<sup>64</sup>

281. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”<sup>65</sup> In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.<sup>66</sup> Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.<sup>67</sup> Moreover, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was recently published on March 6, 2018, in the Journal of the American Medical Association. The study reported that “[t]here was no significant difference in pain-related function between the 2 groups” – those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and other non-steroidal anti-

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<sup>64</sup> Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, New England Journal of Medicine, at 1503 (Apr. 21, 2016)

<sup>65</sup> Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at <http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>.

<sup>66</sup> Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) *Spine* 2219-27 (Sept. 15, 2008).

<sup>67</sup> Franklin, GM, Stover, BD, Turner, JA, Fulton-Kehoe, D, Wickizer, TM, *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 *Spine* 199, 201-202.

inflammatory drugs (“NSAIDs”) like ibuprofen. Accordingly, the study concluded: “Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months.”

**g. Falsehood #7: Alternative forms of pain relief pose greater risks than opioids**

282. In materials they produced, sponsored, or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

283. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Marketing Defendants routinely ignored the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;”<sup>68</sup> hormonal dysfunction;<sup>69</sup> decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;<sup>70</sup> neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.<sup>71</sup>

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<sup>68</sup> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

<sup>69</sup> H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) *J. Pain* 377-84 (2001).

<sup>70</sup> See Bernhard M. Kuschel, *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, *Eur. J. Pub. H.* (July 31, 2014).

<sup>71</sup> Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) *J. Am. Med. Ass’n* 940-47 (2012).

284. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is closer to 3,200.<sup>72</sup>

285. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), that listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

286. Endo's NIPC website, *Painknowledge.com*, which contained a flyer called "*Pain: Opioid Therapy*." This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

287. As another example, the Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk

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<sup>72</sup> Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004).

of opioids on older adults, claiming opioids have “possibly less potential for abuse than in younger patients,” and does not list overdose among the adverse effects. Some of those misrepresentations are described above; others are laid out below.

288. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain.”<sup>73</sup> The article asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.<sup>74</sup>

289. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

290. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

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<sup>73</sup> Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, *Pain Med. News*.

<sup>74</sup> *Id.*

291. As a result of the Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.<sup>75</sup>

**h. Falsehood #8: OxyContin provides twelve hours of pain relief**

292. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provides the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

293. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart:

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<sup>75</sup> M. Daubresse, *et al.*, *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* J. Mafi, *et al.*, *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

## OxyContin PI Figure, Linear y-axis

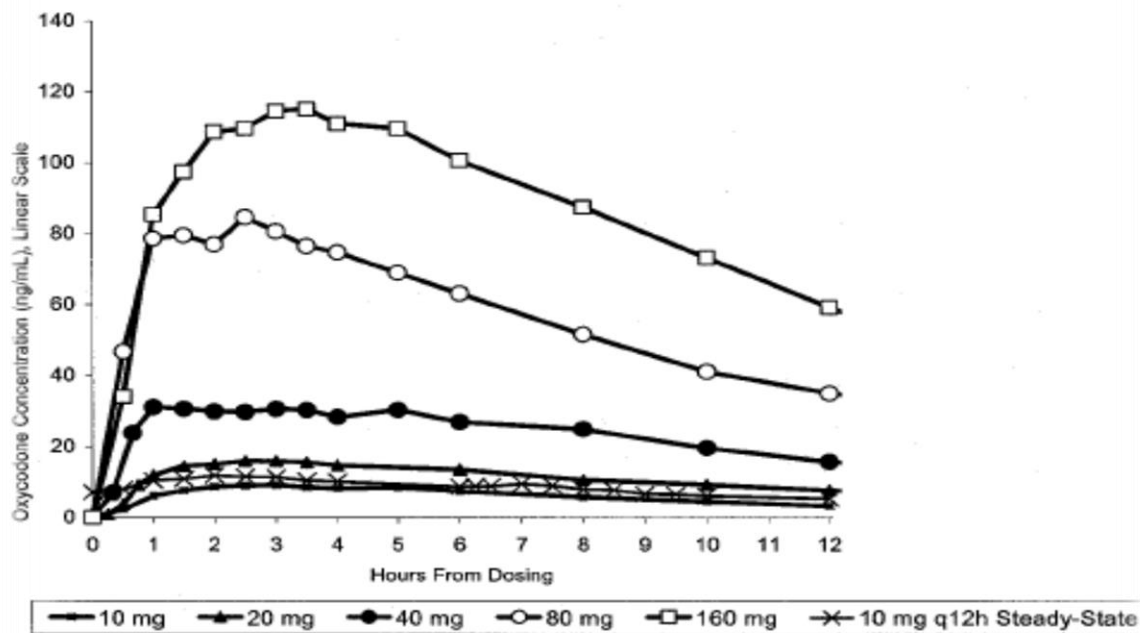


Figure 1

294. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

295. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as “end of dose”



failure. (The FDA found in 2008 that a “substantial number” of chronic pain patients will experience end-of-dose failure with OxyContin.)

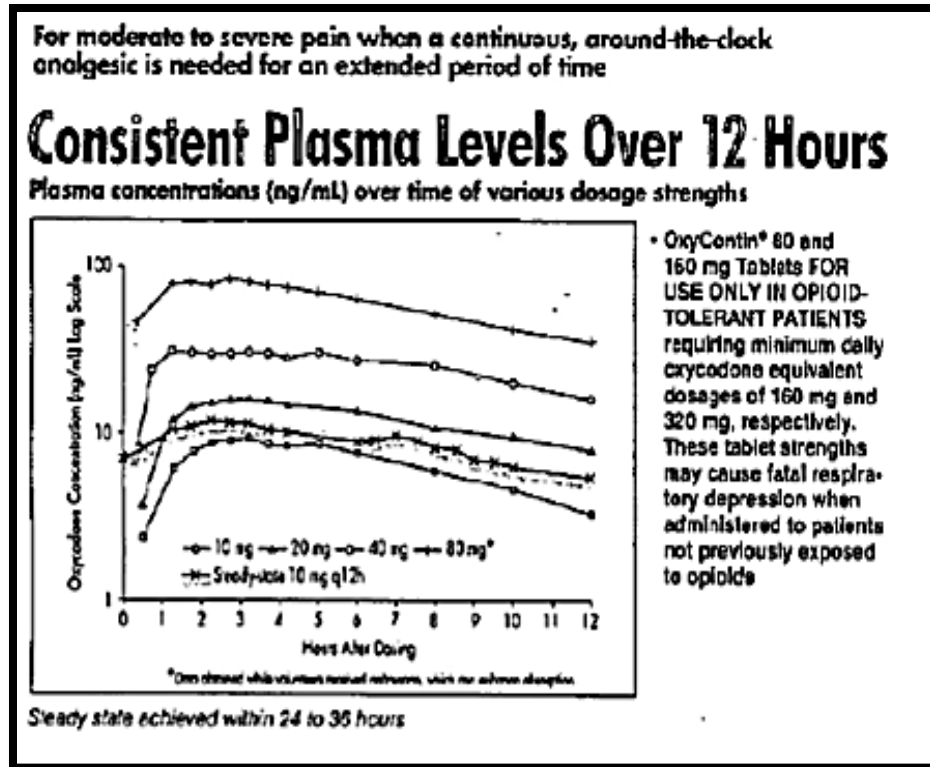
296. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the perfect recipe for addiction.”<sup>76</sup> Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

297. It was Purdue’s decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” that is because Purdue has conducted no such studies.

298. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table’s y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:

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<sup>76</sup> Harriet Ryan, “‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem,” Los Angeles Times, May 5, 2016, available at <http://www.latimes.com/projects/oxycontin-part1/>.



299. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."<sup>77</sup>

300. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of

<sup>77</sup> *OxyContin launch*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/oxycontin-launch-1995/>

acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. It also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. (Urging higher doses to avoid end-of-dose failure is like advising a pilot to avoid a crash by flying higher.) Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”<sup>78</sup>

301. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue’s competitors, but was not disclosed to prescribers. Purdue’s knowledge of some pain specialists’ tendency to prescribe OxyContin three times per day instead of two was set out in Purdue’s internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.

302. Even Purdue’s competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering “durable” pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to “real” 12-hour dosing.

303. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should “convinc[e] the physician that there is no need” for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and

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<sup>78</sup> CDC Guideline at 16.

instead the solution is prescribing higher doses.”<sup>79</sup> One sales manager instructed her team that anything shorter than 12-hour dosing “needs to be nipped in the bud. NOW!!”<sup>80</sup>

304. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue’s competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

**i. Falsehood #9: New formulations of certain opioids successfully deter abuse**

305. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as a competitive opportunity. These companies developed and oversold “abuse-deterrent formulations” (“ADF”) opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants’ false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

306. The CDC Guideline confirms that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies “do not prevent opioid abuse through oral intake, the most common route of

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<sup>79</sup> *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>.

<sup>80</sup> Harriet Ryan, Lisa Girion, and Scott Glover, ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem* (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

opioid abuse, and can still be abused by non-oral routes.” Tom Frieden, the former Director of the CDC, reported that his staff could not find “any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death.”

**i. Purdue’s deceptive marketing of reformulated OxyContin and Hysingla ER**

307. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

308. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue’s market share and the price it could charge. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

309. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

- claimed that Purdue’s ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;
- claimed that Purdue’s ADF opioids reduce opioid abuse and diversion;
- asserted or suggested that its ADF opioids are non-addictive or less addictive,

- asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

310. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug, but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

311. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with and abused.

312. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

313. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to do so orally after the reformulation rather than shift to other drugs.

314. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, it but ignored important negative findings. The study revealed that abuse merely shifted to other drugs and

that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

315. Websites and message boards used by drug abusers, such as [bluelight.org](http://bluelight.org) and [reddit.com](http://reddit.com), report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

316. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

317. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."<sup>81</sup> Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

318. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health

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<sup>81</sup> Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

**ii. Endo's deceptive marketing of reformulated Opana ER**

319. Endo also made abuse-deterrence a key to its marketing strategy.

320. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

321. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

322. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent.

323. However, Endo continued to market Opana ER as ADF while its commercial window remained open.

324. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant injection by syringe. Borrowing



a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

325. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to \$135 million per year. Endo also claimed that if the FDA did not block generic competition, \$125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.<sup>82</sup> The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."<sup>83</sup>

326. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."<sup>84</sup>

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<sup>82</sup> Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec. 14, 2012).

<sup>83</sup> Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

<sup>84</sup> *Id.*; Endo News Release, Sept. 6, 2012 *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012)..

327. In its citizen petition, Endo asserted that redesigned Opana ER had “safety advantages.” Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, “where children unintentionally chew the tablets prior to an accidental ingestion.”<sup>85</sup>

328. However, in rejecting the petition in a 2013 decision, the FDA found that “study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing.” The FDA also determined that “reformulated Opana ER” could also be “readily prepared for injections and more easily injected[.]” In fact, the FDA warned that preliminary data—including in Endo’s own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

329. Meanwhile, in 2012, an internal memorandum to Endo account executives noted that abuse of Opana ER had “increased significantly” in the wake of the purportedly abuse-deterrent formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc., which gathers information from substance abusers entering treatment and reviews abuse-focused internet discussions, that confirmed continued abuse, particularly by injection.

330. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%. Endo’s own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by

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<sup>85</sup> CP, FDA Docket 2012-8-0895, at 2.

injection, compared with 36% for the old formulation.<sup>86</sup> The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

331. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

332. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. Upon information and belief, based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

333. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

334. In its written materials, Endo marketed Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-

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<sup>86</sup> Theresa Cassidy, *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxycodone and Abuse-Deterrent Opioid Formulations*, Pain Week Abstract 2014, available at: <https://www.painweek.org/assets/documents/general/724-painweek2014acceptedabstracts.pdf>.

resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced, “the completion of the company’s transition of its Opana ER franchise to the new formulation designed to be crush resistant.”

335. The press release further stated that: “We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers.” The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed “INTAC Technology” and continued to describe the drug as “designed to be crush-resistant.”

336. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was “designed to be crush resistant.” A January 2013 article in *Pain Medicine News*, based in part on an Endo press release, described Opana ER as “crush-resistant.” This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

337. In March 2017, because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.<sup>87</sup> Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.<sup>88</sup> However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it “has taken significant steps over the years to combat misuse and abuse.”

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<sup>87</sup> Press Release, “FDA requests removal of Opana ER for risks related to abuse,” June 8, 2017, *available at*:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>

<sup>88</sup> Press Release, “Endo Provides Update on Opana ER,” July 6, 2017, *available at*:

<http://www.endo.com/news-events/press-releases>

**iii. Other Marketing Defendants' misrepresentations regarding abuse deterrence**

338. Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was. However, Actavis sales representatives informed prescribers it was more difficult to abuse and less addictive than other opioids.

339. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."<sup>89</sup> One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."<sup>90</sup>

340. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."<sup>91</sup> In anticipation

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<sup>89</sup> Mallinckrodt Press Release, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159>

<sup>90</sup> <http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandanalgesicdrugproductsadvisorycommittee/ucm187490.pdf> at 157-58

<sup>91</sup> Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014)

of Xartemis XR’s approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate “hundreds of millions in revenue.”<sup>92</sup>

341. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their “technology” addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

342. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was not supported by or was contrary to the scientific evidence. In addition, the misrepresentations and omissions set forth above and elsewhere in this Complaint are misleading and contrary to the Marketing Defendants’ products’ labels.

## **2. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels**

343. The Marketing Defendants’ false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

344. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) “Front Groups” with the appearance of independence from the Marketing Defendants; (2) so-called “key opinion leaders” (“KOLs”), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising;

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<sup>92</sup> Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Business Journal (Dec. 30, 2013), available at <http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>

(6) publications; (7) direct, targeted communications with prescribers by sales representatives or “detailers”; and (8) speakers bureaus and programs.

**a. The Marketing Defendants Directed Front Groups to Deceptively Promote Opioid Use**

345. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These “Front Groups” put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.<sup>93</sup> Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

346. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”<sup>94</sup> “Even small organizations—with ‘their large numbers and credibility with policymakers and the public’—have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”<sup>95</sup>

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<sup>93</sup> U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, (February 12, 2018) <https://www.hsdl.org/?abstract&did=808171> (“Fueling an Epidemic”), at p. 3.

<sup>94</sup> *Id.* at p. 2.

<sup>95</sup> *Id.*

Indeed, the U.S. Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,<sup>96</sup> which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, “provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy,”<sup>97</sup> found that the Marketing Defendants made millions of dollars’ worth of contributions to various Front Groups.<sup>98</sup>

347. The Marketing Defendants also “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.<sup>99</sup>

348. As the Senate *Fueling an Epidemic* Report found, the Front Groups “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”<sup>100</sup> They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding.”<sup>101</sup>

349. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that

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<sup>96</sup> *Fueling an Epidemic*, *supra* note 125, p. 3.

<sup>97</sup> *Id.* at p. 1.

<sup>98</sup> *Id.* at p. 3.

<sup>99</sup> *Id.* at p. 10.

<sup>100</sup> *Id.* at 12-15.

<sup>101</sup> *Id.* at 12.



Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each other to deceptively promote the use of opioids for the treatment of chronic pain.

**i. American Pain Foundation**

350. The most prominent of the Front Groups was the American Pain Foundation (“APF”). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF’s largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

351. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use, which are discussed below.

352. APF also developed the National Initiative on Pain Control (“NIPC”), which ran a facially unaffiliated website, [www.painknowledge.com](http://www.painknowledge.com). NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of “dinner dialogues.” But it was Endo that

substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.painknowledge.org*. Endo estimated it would reach 60,000 prescribers through NIPC.

353. APF was often called upon to provide "patient representatives" for the Marketing Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that share [its] business interests.

354. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

355. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the

terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

356. APF's Board of Directors was largely comprised of doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Marketing Defendants demonstrates APF's clear lack of independence, in its finances, management, and mission, and its willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: “[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence.”

357. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective immediately.” Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

**ii. American Academy of Pain Medicine and the American Pain Society**

358. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.<sup>102</sup> The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

359. AAPM’s corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM’s past presidents include Haddox (1998), Dr. Scott Fishman (“Fishman”) (2005), Dr. Perry G. Fine (“Fine”) (2011) and Dr. Lynn R. Webster (“Webster”) (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

360. Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”<sup>103</sup>

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<sup>102</sup> *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997). Available at <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (as viewed August 18, 2017).

<sup>103</sup> Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

361. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

362. AAPM describes the annual event as an “exclusive venue” for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

363. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

364. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”) AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

365. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug

companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

366. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

367. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."<sup>104</sup>

368. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

369. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the*

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<sup>104</sup> 2016 CDC Guideline at 2.

*Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

### iii. FSMB

370. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

371. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

372. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

373. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in and around Plaintiff’s geographical area.

374. FSMB’s 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The

publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as “the leading continuing medical education (CME) activity for prescribers of opioid medications.” This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.<sup>105</sup>

375. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

#### **iv. The Alliance for Patient Access**

376. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.”<sup>106</sup> It is run by Woodberry Associates LLC, a lobbying firm that was also established in

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<sup>105</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide* 8-9 (Waterford Life Sciences 2007).

<sup>106</sup> *About AfPA*, The Alliance for Patient Access, <http://allianceforpatientaccess.org/about-afpa/#membership> (last visited Jan. 4, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.



2006.<sup>107</sup> As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon.

377. APA’s board members have also directly received substantial funding from pharmaceutical companies.<sup>108</sup> For instance, board vice president Dr. Srinivas Nalamachu (“Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.<sup>109</sup> Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

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<sup>107</sup> Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma’s agenda*, Health News Review (Oct. 2, 2017), <https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/> (hereinafter “Jaklevic, *Non-profit Alliance for Patient Access*”).

<sup>108</sup> All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica’s Dollars for Docs database, available at <https://projects.propublica.org/docdollars/>.

<sup>109</sup> Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas City Star (July 20, 2017), <http://www.kansascity.com/news/business/health-care/article162569383.html>.

378. Among its activities, APA issued a “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.”<sup>110</sup> Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

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In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening, and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.<sup>111</sup>

379. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased

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<sup>110</sup> Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access (Oct. 2013), <https://goo.gl/EiSYhW>.

<sup>111</sup> *Id.* at 4-5 (footnote omitted).

record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.<sup>112</sup>

380. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.<sup>113</sup>

381. In conclusion, the white paper states that “[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”<sup>114</sup>

382. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA’s agenda.<sup>115</sup>

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<sup>112</sup> *Id.* at 5-6.

<sup>113</sup> *Id.* at 6.

<sup>114</sup> *Id.* at 7.

<sup>115</sup> Jaklevic, *Non-profit Alliance for Patient Access*, *supra* n.74.

383. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the “suspicious orders” provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* (“CSA” or “Controlled Substances Act”). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice (“DOJ”) memo stated that the proposed bill ““could actually result in increased diversion, abuse, and public health and safety consequences””<sup>116</sup> and, according to DEA chief administrative law judge John J. Mulrooney (“Mulrooney”), the law would make it “all but logically impossible” to prosecute manufacturers and distributors, like the defendants here, in the federal courts.<sup>117</sup> The law passed both houses of Congress and was signed into law in 2016.

**v. The U.S. Pain Foundation (“USPF”)**

384. The USPF was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone.<sup>118</sup> The USPF was also a critical component of the Marketing Defendants’ lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as “Platinum,”

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<sup>116</sup> Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/> (hereinafter, “Whitaker, Opioid Crisis Fueled by Drug Industry”).

<sup>117</sup> John J. Mulrooney, II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marquette L. Rev. (forthcoming Feb. 2018), <https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html>.

<sup>118</sup> *Fueling an Epidemic*, *supra* note 125, p. 4.

“Gold,” and “Basic” corporate members.<sup>119</sup> Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

**vi. American Geriatrics Society (“AGS”)**

385. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter “2002 AGS Guidelines”) and 2009 (Pharmacological Management of Persistent Pain in Older Persons,<sup>120</sup> hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.<sup>121</sup> AGS’s complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

386. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong

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<sup>119</sup> *Id.* at 12; Transparency, U.S. Pain Foundation, <https://uspainfoundation.org/transparency/> (last accessed on March 9, 2018).

<sup>120</sup> *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last accessed on March 9, 2018).

<sup>121</sup> John Fauber & Ellen Gabler, “Narcotic Painkiller Use Booming Among Elderly,” *Milwaukee J. Sentinel*, May 30, 2012.

recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.<sup>122</sup> These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

387. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts, and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

388. Members of AGS Board of Directors were doctors who were on the Marketing Defendants’ payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

**b. The Marketing Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use**

389. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants’ well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the

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<sup>122</sup> 2009 AGS Guidelines at 1342.

wider and broader use of opioids. These doctors include Dr. Russell Portenoy and Dr. Lynn Webster, as set forth in this section, as well as Dr. Perry Fine and Dr. Scott Fishman, as set forth further below.

390. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

391. As the Marketing Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

392. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.

393. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

394. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The

Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Marketing Defendants kept these KOLs well-funded to enable them to push the Marketing Defendants' deceptive message out to the medical community.

395. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

396. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

**i. Dr. Russell Portenoy**

397. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew



substantial gains in employment or social function could be attributed to the institution of opioid therapy.”<sup>123</sup>

398. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

*The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*<sup>124</sup>

(emphasis added.) According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”<sup>125</sup>

399. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids, and minimizing their risks. A respected leader in the field of pain

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<sup>123</sup> R. Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).

<sup>124</sup> R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

<sup>125</sup> *Id.*

treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”<sup>126</sup>

400. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”<sup>127</sup>

401. Dr. Portenoy was also a critical component of the Marketing Defendants’ control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

402. In recent years, some of the Marketing Defendants’ KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.<sup>128</sup> Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.”<sup>129</sup> He

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<sup>126</sup> Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* 314 (Bloomsbury Press 2015).

<sup>127</sup> *Id.* at 136.

<sup>128</sup> See, e.g., John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

<sup>129</sup> Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012, 11:36am), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

mused, “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . .”<sup>130</sup>

403. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not “real” and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn’t before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*<sup>131</sup>

404. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: “It was pseudoscience. I guess I’m going to have always to live with that one.”<sup>132</sup>

## ii. Dr. Lynn Webster

405. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo’s special advertising supplements touting Opana ER. Dr. Webster was the author of

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<sup>130</sup> *Id.*

<sup>131</sup> Jacobs, *One-paragraph letter*, supra n.25; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

<sup>132</sup> Meier, supra note 16, at 277.

numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

406. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors throughout the United States, including in and around Plaintiff's geographical area.

407. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

408. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of

breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP.” This CME effectively amounted to off-label promotion of Cephalon’s opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

409. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

### iii. Dr. Perry Fine

410. Dr. Perry Fine’s ties to the Marketing Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue’s advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.<sup>133</sup>

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<sup>133</sup> Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>.

411. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

412. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson’s website states that the company paid him \$32,017 for consulting, promotional talks, meals and travel that year.<sup>134</sup>

413. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.<sup>135</sup>

414. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic

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<sup>134</sup> Weber and Ornstein, *supra* note 61.

<sup>135</sup> Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

Pain: An 18-Month Study.”<sup>136</sup> In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”<sup>137</sup>

415. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”<sup>138</sup>

416. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.<sup>139</sup> He states the “goal is to improve effectiveness

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<sup>136</sup> Perry G. Fine, *et al.*, *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

<sup>139</sup> Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), [https://www.youtube.com/watch?v=\\_G3II9yqgXI](https://www.youtube.com/watch?v=_G3II9yqgXI).

which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years*.” The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”<sup>140</sup>

#### iv. Dr. Scott Fishman

417. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”<sup>141</sup>

418. Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled “Responsible Opioid Prescribing,” in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

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<sup>140</sup> *Id.*

<sup>141</sup> Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry> (hereinafter “Weber, *Two Leaders in Pain*”).



419. In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it’s critical to remember that the problem of unrelieved pain remains as urgent as ever.<sup>142</sup>

420. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins.”<sup>143</sup>

421. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical coper’ and an addict.”<sup>144</sup> The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

c. **The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs**

422. Now that the Marketing Defendants had both a group of physician promoters and had built a false body of “literature,” Defendants needed to make sure their false marketing message was widely distributed.

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<sup>142</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

<sup>143</sup> *Id.*

<sup>144</sup> Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

423. One way the Marketing Defendants aggressively distributed their false message was through thousands of Continuing Medical Education courses (“CMEs”).

424. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations’ conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.

425. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants’ deceptions.

426. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy, and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

427. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and which disseminated false and misleading information to physicians across the country.

428. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who “previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway.”<sup>145</sup> The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

429. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

430. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

431. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

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<sup>145</sup> Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, <http://www.medscape.org/viewarticle/461612> (last visited Oct. 10, 2017).

432. The American Medical Association (“AMA”) recognized the impropriety that pharmaceutical company-funded CMEs creates; stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urges that “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”<sup>146</sup>

433. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

434. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers’ views on opioids. Producers of CMEs and the Marketing Defendants both measure the effects of CMEs on prescribers’ views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

**d. The Marketing Defendants Used “Branded” Advertising to Promote their Products to Doctors and Consumers**

435. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of*

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<sup>146</sup> Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n (Nov. 2011).

*Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. The Marketing Defendants collectively spent more than \$14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

436. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.<sup>147</sup> They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.<sup>148</sup> Endo’s research, for example, also found that such communications resulted in greater patient “brand loyalty,” with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused “education and support” materials in the form of pamphlets, videos, or other publications that patients could view in their physician’s office.

**e. The Marketing Defendants Used “Unbranded” Advertising To Promote Opioid Use For Chronic Pain Without FDA Review**

437. The Marketing Defendants also aggressively promoted opioids through “unbranded advertising” to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease awareness”—encouraging consumers to “talk to your doctor” about a certain health condition

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<sup>147</sup> In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

<sup>148</sup> *Id.*

without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

438. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

**f. The Marketing Defendants Funded, Edited And Distributed Publications That Supported Their Misrepresentations**

439. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

440. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

441. The Marketing Defendants’ plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Marketing Defendants’ marketing departments.

442. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

443. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

444. For example, in 2007 Cephalon sponsored the publication of an article titled “Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,”<sup>149</sup> published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article’s authors (including Dr. Lynn Webster,

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<sup>149</sup> Donald R. Taylor, *et al.*, *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) *Pain Med.* 281-88 (Mar. 2007).

discussed above) stated that the “OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.<sup>150</sup>

**g. The Marketing Defendants Used Detailing To Directly Disseminate Their Misrepresentations To Prescribers**

445. The Marketing Defendants’ sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with centrally orchestrated messages. The Marketing Defendants’ sales representatives also distributed third-party marketing material to their target audience that was deceptive.

446. Each Marketing Defendant promoted opioids through sales representatives (also called “detailers”) and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

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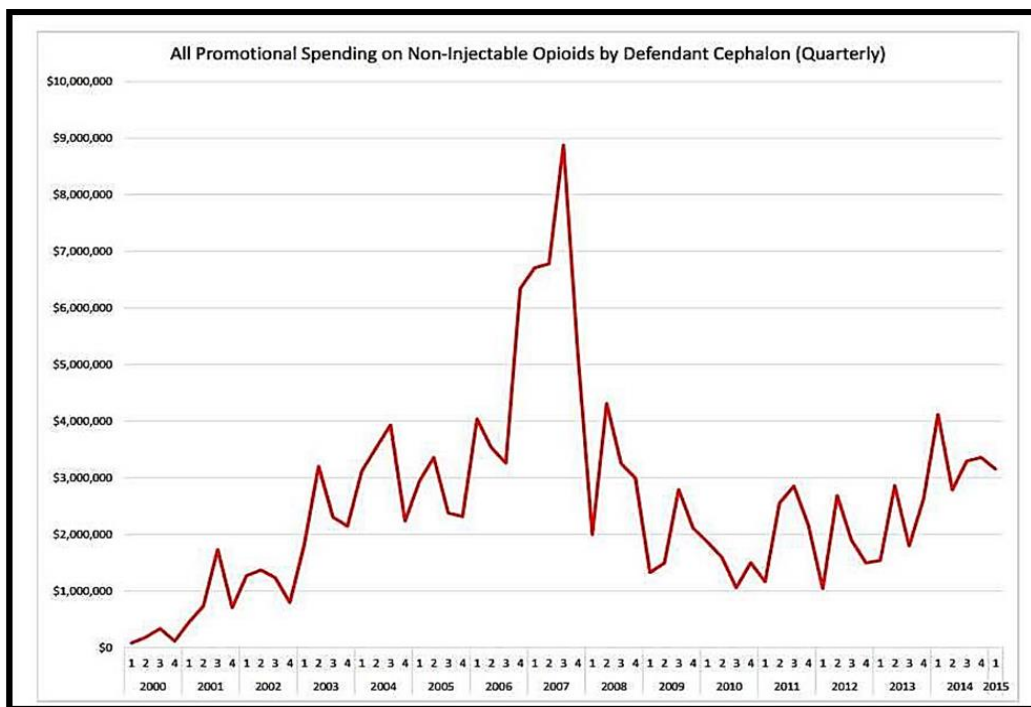
<sup>150</sup> *Id.*



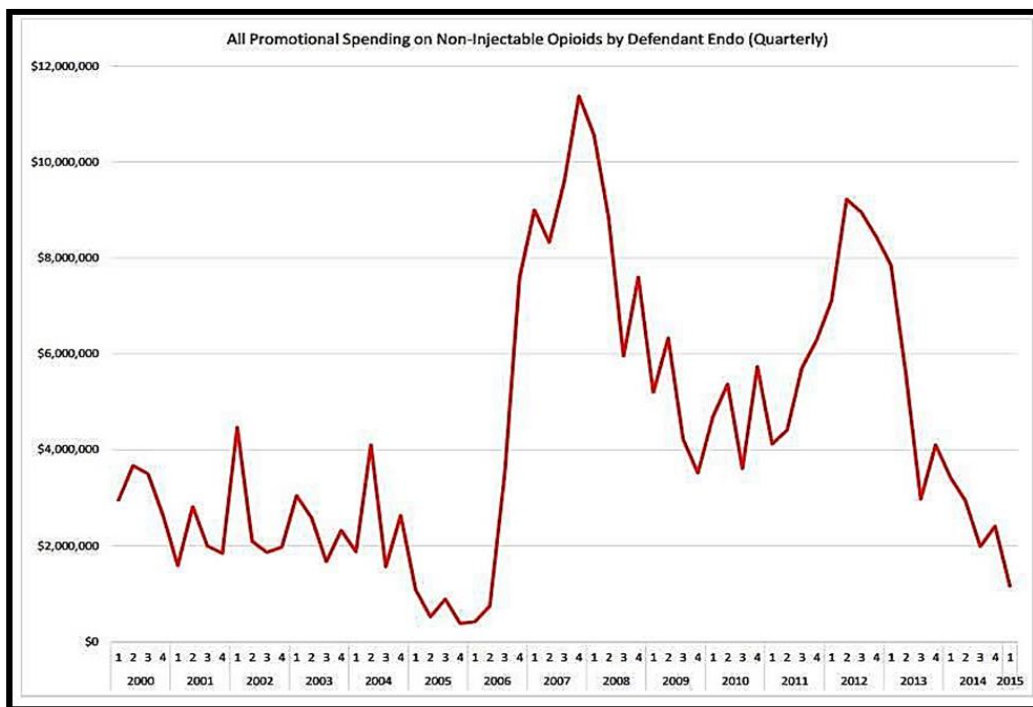
447. In accordance with common industry practice, the Marketing Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

448. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

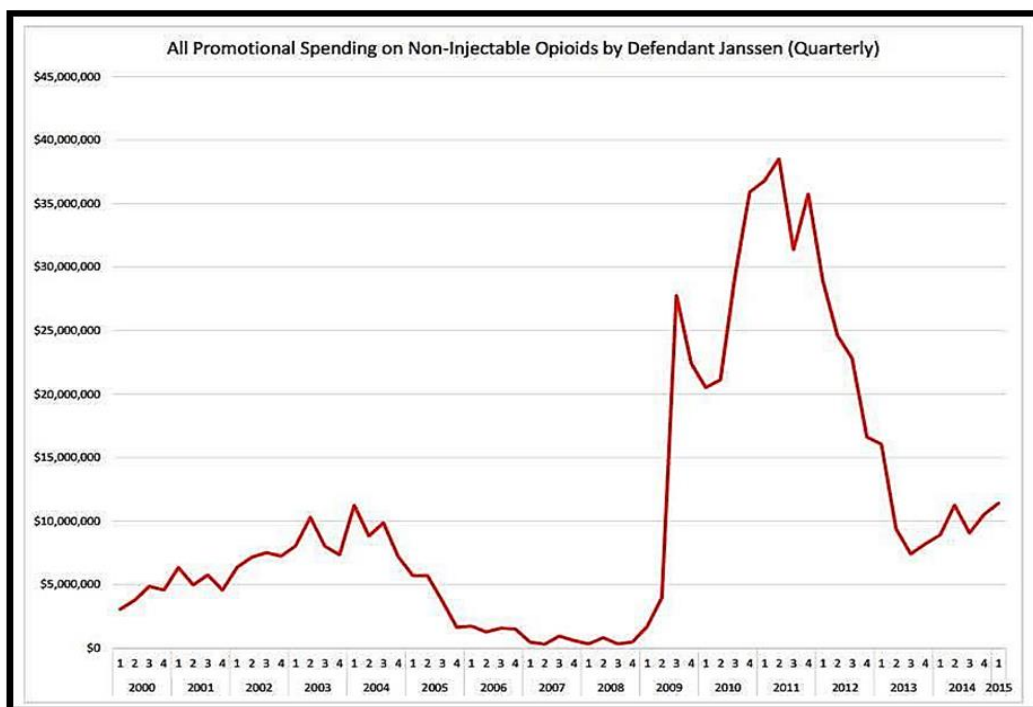
449. Cephalon's quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:



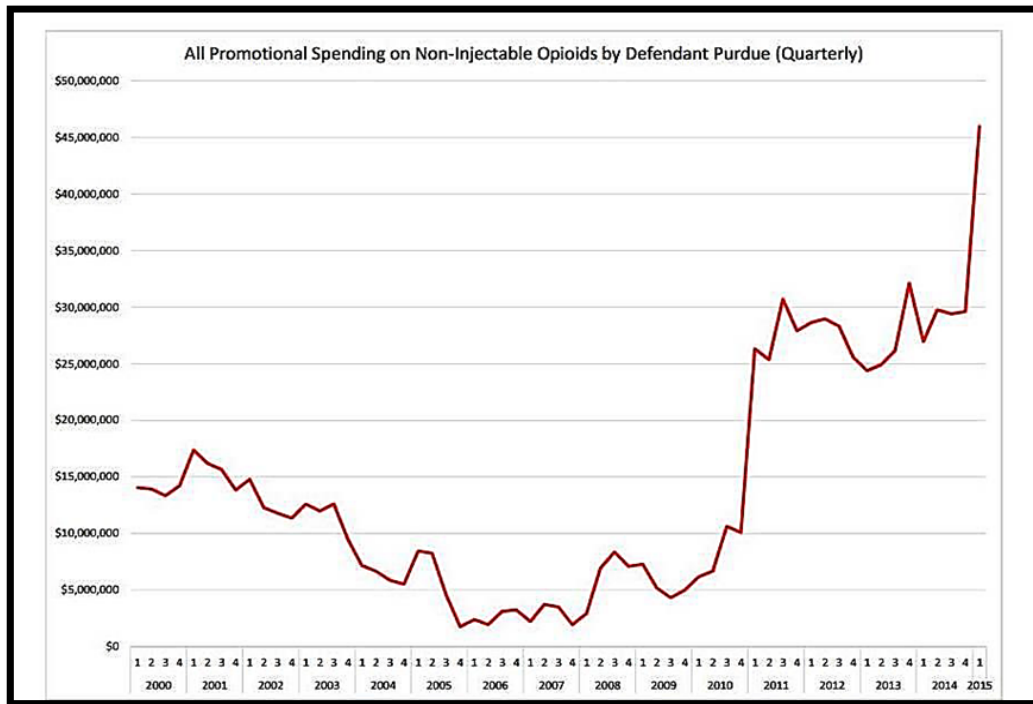
450. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year):



451. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



452. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above \$25 million in 2011 (for a total of \$110 million that year), and continues to rise, as shown below:



453. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

**h. Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages**

454. In addition to making sales calls, Marketers' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The

Marketing Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

455. As detailed below, Insys paid prescribers for *fake* speakers' programs in exchange for prescribing its product, Subsys. Insys's schemes resulted in countless speakers' programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales representative. It was a pay-to-prescribe program.

456. Insys used speakers' programs as a front to pay for prescriptions, and paid to push opioids onto patients who did not need them.

### **3. The Marketing Defendants Targeted Vulnerable Populations**

457. The Marketing Defendants specifically targeted their marketing at two vulnerable populations—the elderly and veterans.

458. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression which occurs more frequently in elderly patients.

459. The Marketing Defendants promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. The AGS 2009 Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as “*exceedingly low* in older patients with no current or past history of substance abuse.” (emphasis added). As another example, an Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, taught that prescribing opioids to older patients carried

“possibly less potential for abuse than in younger patients.” Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

460. According to a study published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

461. Yet the Marketing Defendants deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as “underused” and the “gold standard of pain medications” while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from the two drugs together.

462. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

**4. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys**

463. Insys's opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

464. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Cephalon's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them."<sup>151</sup> Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

465. Since its launch, Subsys has been an extremely expensive medication, and its price continues to rise each year. Depending on a patient's dose strength and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

466. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority

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<sup>151</sup> Press Release, FDA, *FDA Approves Shared System REMS for TIRF Products*, Dec. 29, 2011.

Staff Report (“Staff Report”), the prior authorization process includes “confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . .”<sup>152</sup>

467. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (“IRC”), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients’ diagnoses and medical conditions.

468. Subsys has proved to be extremely profitable for Insys. Insys made approximately \$330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

469. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment those

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<sup>152</sup> U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*, <https://www.documentcloud.org/documents/3987564-REPORT-Fueling-an-Epidemic-Insys-Therapeutics.html>.



conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers' programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

470. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.<sup>153</sup>

471. The Insys "speakers program" was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks."<sup>154</sup> It was a pay-to-prescribe program.

472. Insys's sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

473. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers

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<sup>153</sup> *Id.*

<sup>154</sup> Roddy Boyd, *Insys Therapeutics and the New 'Killing It'*, Southern Investigative Reporting Foundation, The Investigator, April 24, 2015.

of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20 years in prison.

474. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving \$83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately \$1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

475. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

476. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at

upscale restaurants in the Chicago area, and Illinois speakers received an “honorarium” ranging from \$700 to \$5,100, and they were allowed to order as much food and alcohol as they wanted. At most of the events, the “speaker” being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

477. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys’s founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. A U.S. Department of Justice press release explained that, among other things: “Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis.”<sup>155</sup> A Drug Enforcement Administration (“DEA”) Special Agent in Charge further explained that: “Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers’ health and safety and, indeed, very lives depend on it.”<sup>156</sup>

**5. The Marketing Defendants’ Scheme Succeeded, Creating a Public Health Epidemic**

**a. The Marketing Defendants dramatically expanded opioid prescribing and use**

478. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand

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<sup>155</sup> Press Release, DOJ, U.S. Attorney’s Office, Dist. of Mass., *Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct. 26, 2017), available at <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

<sup>156</sup> *Id.*

their success. They knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

479. Endo, for example directed the majority of its marketing budget to sales representatives—with good results: virtually all of Endo’s opioid sales—and profits—were from a market that did not exist ten years earlier.

480. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”<sup>157</sup> Actiq became Cephalon’s second best-selling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million.<sup>158</sup> Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”<sup>159</sup>

481. Upon information and belief, each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors’ perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors’ prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs. Defendants invested in their aggressive and deceptive

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<sup>157</sup> Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

<sup>158</sup> Carreyrou, *Narcotic Lollipop*.

<sup>159</sup> *Id.*

marketing for one reason: it worked. As described in this Complaint, both in specific instances and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them to continue prescribing opioids or to switch to supposedly "safer" opioids, such as ADF.

482. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.<sup>160</sup> The effects of sales calls on prescribers' behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

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<sup>160</sup> See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

483. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.<sup>161</sup> These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

484. Thus, both independent studies and Marketing Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

**b. Marketing Defendants' deception in expanding their market created and fueled the opioid epidemic**

485. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."<sup>162</sup> It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

486. There is a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and

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<sup>161</sup> Research Letter, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

<sup>162</sup> Theodore J. Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16.8 *Pharmacoepidemiology and Drug Safety*, 827-40 (2007).

associated adverse outcomes. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”<sup>163</sup>

487. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

**E. Defendants Throughout the Supply Chain Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report, and Take Steps to Halt Suspicious Orders**

488. The Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

489. For over a decade, as the Marketing Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

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<sup>163</sup> <http://www.nejm.org/doi/full/10.1056/NEJMSr1601307>

490. Defendants are all required to register as either manufacturers or distributors pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74.

491. Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent (“MME”) per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

492. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”<sup>164</sup> Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”<sup>165</sup>

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<sup>164</sup> CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al.* “Increases in drug and opioid overdose deaths—United States, 2000–2014.” *American Journal of Transplantation* 16.4 (2016): 1323-1327.

<sup>165</sup> *Id.*



**1. All Defendants Have a Duty to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions**

493. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

494. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding New Mexico with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

495. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

496. Third, each of the Defendants was required to register with the DEA to manufacture and/or distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. As registrants, Defendants were required to “maint[ain] . . . effective controls against diversion” and to “design and operate a system to disclose . . . suspicious orders of controlled substances.” 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. Defendants were further required to take steps to halt suspicious orders. Defendants violated their obligations under federal law.

497. Fourth, Defendants also had duties under applicable state laws.

498. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled

substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances – must adhere to the specific security, recordkeeping, monitoring, and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

499. The CSA requires manufacturers and distributors of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

500. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.” When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class [of each drug] by all manufacturers;

- c. Trends in the national rate of disposal of the basic class [of drug];
- d. An applicant's production cycle and current inventory position;
- e. Total actual or estimated inventories of the class [of drug] and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

501. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

502. To ensure that even drugs produced within quota are not diverted, Federal regulations issued under the CSA mandate that all registrants, manufacturers, and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

503. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to

trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

504. In sum, Defendants have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

505. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that Distributor and Marketing Defendants alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

506. Further, these laws and industry guidelines make clear that the Distributor Defendants and Marketing Defendants alike have a duty and responsibility to exercise their

specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

507. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc., and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

508. Marketing Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS. Their extensive boots-on-the-ground through their sales force, allows Marketing Defendants to

observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Marketing Defendants regularly mined data, including, upon information, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing, that would have alerted them, independent of their sales representatives, to suspicious prescribing. These information points gave Marketing Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

509. Defendants have a duty to, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

510. Defendants breached these duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

**2. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders**

511. The reason for the reporting rules is to create a “closed” system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market,

distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

512. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

513. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

514. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA"), now known as the Healthcare Distribution Alliance ("HDA"), a trade association of pharmaceutical distributors to which Distributor Defendants belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations to do so, but "as responsible members of society."

Guidelines established by the HDA also explain that distributors, “[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”

515. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

516. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are “one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.” The DEA’s September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.” The same letter reminds distributors of the



importance of their obligation to “be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes,” and warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

517. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers, and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” The DEA’s December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”

### **3. Defendants Worked Together to Inflate the Quotas of Opioids They Could Distribute**

518. Finding it impossible to legally achieve their ever-increasing sales ambitions Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

519. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Marketing Defendants and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by

manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, “[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers’ stock.” *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able “to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers.” Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

520. Distributor Defendants had financial incentives from the Marketing Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the HDA includes a “Contracts and Chargebacks Working Group,” suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt, a prescription opioid manufacturer, acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers

(distributors).” The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants,” meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

521. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The manufacturers negotiated agreements whereby the Marketing Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

522. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum (“PCF”) and the HDA.

523. The Pain Care Forum (“PCF”) has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

524. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national

response to the ongoing wave of prescription opioid abuse.”<sup>166</sup> Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.<sup>167</sup>

525. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participant in the PCF. In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants worked together through the PCF. But, the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.<sup>168</sup> The Distributor Defendants participated directly in the PCF as well.

526. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants including Actavis, Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA. Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active

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<sup>166</sup> Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee*, Healthcare Distribution Alliance (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/executive-committee>.

membership and participation of the Marketing Defendants by advocating for the many benefits of members, including “strengthen[ing] . . . alliances.”<sup>169</sup>

527. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”<sup>170</sup> Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Marketing and Distributor Defendants.

528. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s businesses.<sup>171</sup> For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

529. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “most recent year end net sales” through wholesale

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<sup>169</sup> *Manufacturer Membership Benefits*, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

<sup>170</sup> *Id.*

<sup>171</sup> *Manufacturer Membership Application*, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

distributors, including the Distributor Defendants AmerisourceBergen, Cardinal Health, and McKesson and their subsidiaries.

530. The closed meetings of the HDA’s councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

531. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”<sup>172</sup> The conferences also gave the Marketing and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”<sup>173</sup> The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. It is clear that the Marketing Defendants embraced this opportunity by attending and sponsoring these events.<sup>174</sup>

532. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

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<sup>172</sup> *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed on September 14, 2017).

<sup>173</sup> *Id.*

<sup>174</sup> *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-distribution-management-conference> (last accessed on September 14, 2017).

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.
- e. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

533. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.<sup>175</sup> For example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange business transactions between distributors and manufacturers...” The

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<sup>175</sup> *Webinars*, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

Marketing Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

534. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

535. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

536. Publications and guidelines issued by the HDA nevertheless confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the “Industry Compliance Guidelines”) regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.

537. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is “difficult to find the right balance between



proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

538. The Defendants’ scheme had a decision-making structure driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked together to control the state and federal government’s response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

539. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

540. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

541. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other’s compliance with their reporting obligations.

542. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be

brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

543. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

**4. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers**

544. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

545. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

546. This information includes the following facts:

- a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

- d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

547. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

548. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

549. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.<sup>176</sup> The “know your customer” questionnaires informed the Defendants of

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<sup>176</sup> *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration (available at [https://www.dea.gov/diversion/usdoj.gov/mtgs/pharm\\_industry/14th\\_pharm/levinl\\_ques.pdf](https://www.dea.gov/diversion/usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf)); Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA*, footnote continued on next page

the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

550. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.<sup>177</sup>

551. IMS, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.<sup>178</sup>

552. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.<sup>179</sup>

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Purdue Pharma and McGuireWoods LLC, (available at [https://www.mcguirewoods.com/news-resources/publications/lifesciences/product\\_diversion\\_beyond\\_pdma.pdf](https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf)).

<sup>177</sup> A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, \*9-10 (Feb. 22, 2011).

<sup>178</sup> Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, (accessed on February 15, 2018), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf>, Figure 2 at p.3.

<sup>179</sup> *Sorrell v. IMS Health Inc.*, 2011 WL 705207, \*467-471 (Feb. 22, 2011).

553. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the used the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.<sup>180</sup>

554. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

555. Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012<sup>181</sup> and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders, all for failure to report suspicious orders.<sup>182</sup>

556. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

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<sup>180</sup> In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id*; see also Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at \*204 (Feb. 22, 2011).

<sup>181</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

<sup>182</sup> *Id*.

Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

557. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.<sup>183</sup> In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."<sup>184</sup>

558. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked

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<sup>183</sup> Meier, *supra* note 16, at 298-300.

<sup>184</sup> *Id.*

like gang members,” and that she felt “very certain that this an organized drug ring[.]”<sup>185</sup> She wrote, “This is clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue responded that while they were “considering all angles,” it was “really up to [the wholesaler] to make the report.”<sup>186</sup> This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

559. Defendant’ obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, but not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants’ sales.

560. Defendants purchased data from IMS (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors’ sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

561. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

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<sup>185</sup> Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, LOS ANGELES TIMES (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycotin-part2/>

<sup>186</sup> *Id.*

562. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Marketing Defendants have consistently blamed “bad actors.” For example, in 2001, during a Congressional hearing, Purdue’s attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was “fooled” by the doctor: “The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us.”<sup>187</sup>

563. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were “fooled.” In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold mine” and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

564. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company’s policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

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<sup>187</sup> Meier, *supra* note 16, at 179.



565. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

**5. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion**

566. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids following into communities across America. Despite the notice described above, and in disregard of their duties, Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report, and take steps to halt suspicious orders.

567. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

568. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, inter alia, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”

569. McKesson further admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers.” Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which investigators found “were supplying pharmacies that sold to criminal drug rings.”

570. Similarly, in 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

571. On December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- a. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)”;
- b. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make

records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

- c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

572. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal Health settled for \$20 million.

573. H.D. Smith has also routinely been found to have violated its duties to report suspicious orders and halt suspicious shipments of prescription opioids. According to a recent letter from the U.S. House of Representatives Committee on Energy and Commerce, data provided to the Committee showed that between 2007 and 2008, H.D. Smith provided two pharmacies in Williamson, WV, a town with a population of 3,191, combined total of nearly 5 million hydrocodone and oxycodone pills - approximately 1,565 hydrocodone and oxycodone pills for every man, woman, and child in Williamson, WV.<sup>188</sup> According to press reports, H.D.

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<sup>188</sup> See January 26, 2018 Letter to J. Christopher Smith, President and CEO, H.D. Smith, from the House Committee on Energy and Commerce.

Smith distributed approximately 13.7 million hydrocodone and 4.4 million oxycodone pills to West Virginia between 2007 and 2012.<sup>189</sup> Press accounts further indicate that H.D. Smith did not submit any suspicious order reports to the state for at least a decade.<sup>190</sup> Upon information and belief, H.D. Smith engaged in similar wrongful activities in and around Plaintiff's geographical area.

574. Thus, it is the various governmental agencies who have alleged or found—and the Defendants themselves who have admitted—that the Defendants, acting in disregard of their duties, pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

**6. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement**

575. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all.

576. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the

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<sup>189</sup> Eric Eyre, *Drug wholesaler agrees to pay \$3.5M to settle WV lawsuit*, Charleston Gazette-Mail, Jan. 3, 2017 available at [https://www.wvgazettemail.com/news/health/drug-wholesaler-agrees-to-pay-m-to-settle-wv-lawsuit/article\\_4e8c7f4c-cec5-5173-a199-c19374a6250c.html](https://www.wvgazettemail.com/news/health/drug-wholesaler-agrees-to-pay-m-to-settle-wv-lawsuit/article_4e8c7f4c-cec5-5173-a199-c19374a6250c.html)

<sup>190</sup> *Id.*

future,” including specific measures delineated in a “Compliance Addendum” to the Settlement. Yet, in 2017, McKesson paid \$150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

577. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,” which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

578. Along the same lines, Defendant McKesson publicly claims that its “customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process,” creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”

579. Defendant AmerisourceBergen, too, has taken the public position that it is “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokeswoman also provided assurance that: “At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

580. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:<sup>191</sup>

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- b. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”

581. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the

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<sup>191</sup> Brief for HDMA and NACDS, 2016 WL 1321983, at \*3-4, \*25.

Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

582. Defendant Mallinckrodt similarly claims to be “committed . . . to fighting opioid misuse and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, . . . .”

583. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive role in the fight against opioid abuse,” including its commitment to ADF opioids and its “strong record of coordination with law enforcement.”<sup>192</sup>

584. At the heart of Purdue’s public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue’s recent pronouncements in response to the opioid abuse.

585. Touting the benefits of ADF opioids, Purdue’s website asserts: “[W]e are acutely aware of the public health risks these powerful medications create . . . . That’s why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid

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<sup>192</sup> Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label*, May 5, 2016, available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-fda-approved-label/>; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>.

abuse and misuse . . . .”<sup>193</sup> Purdue’s statement on “Opioids Corporate Responsibility” likewise states that “[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government.”<sup>194</sup> And, responding to criticism of Purdue’s failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue “ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion.”<sup>195</sup>

586. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

587. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression

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<sup>193</sup> Purdue website, *Opioids With Abuse-Deterrent Properties*, available at <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/>.

<sup>194</sup> Purdue website, *Opioids Corporate Responsibility*, available at <http://www.purduepharma.com/news-media/opioids-corporate-responsibility/>.

<sup>195</sup> Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.



that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

**7. The Chain Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids**

588. Retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and retail sellers of opioids. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

589. Each of the Chain Pharmacies does substantial business across the United States. This business includes the distribution and sale of prescription opioids.

590. ARCOS data confirms that the Chain Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in the County. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to the County. The Chain Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and thus contributed substantially to the diversion problem.

591. The Chain Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, Chain Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, sale, and use of prescription opioids in communities throughout the country, and in the County in particular. They used the data to evaluate their own sales activities and workforce. The Chain Pharmacies also provided data regarding, inter alia, individual doctors to drug companies, which targeted those prescribers with their marketing, in exchange for rebates or other forms of consideration. The Chain Pharmacies'

data is a valuable resource that they could and should have used to help stop diversion, but they failed to do so. Defendants facilitated the supply of far more opioids that could have been justified to serve a legitimate market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, as well as to maintain effective policies and procedures to guard against diversion from their retail stores, breached both their statutory and common law duties.

592. For over a decade, Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers.

593. Defendants are all required to register as distributors or dispensers pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74.

594. Each participant in the supply chain of opioid distribution, including the Chain Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

595. According to the CDC, opioid prescriptions, as measured by number of prescriptions and MME per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. Not all of these prescriptions were legitimate. Yet, Defendants systemically ignored red flags that they were fueling a black market, and failed to maintain effective controls against diversion at both the wholesale and pharmacy level. Instead, they put profits over the public health and safety. Despite their legal obligations as

registrants under the CSA, the Chain Pharmacies allowed widespread diversion to occur—and they did so knowingly.

596. Upon information and belief, this problem was compounded by the Chain Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate and what measures and/or actions to take when a prescription is identified as potentially illegitimate.

597. Upon information and belief, the Chain Pharmacies also failed to put in place effective policies and procedures to prevent their stores from facilitating diversion and selling into a black market, and to conduct adequate internal or external reviews of their opioid sales to identify patterns regarding prescriptions that should not have been filled, or if they conducted such reviews, they failed to take any meaningful action as a result.

598. Upon information and belief, even where Chain Pharmacies enacted policies and procedures to prevent stores from facilitating diversion and selling into a black market, such policies were merely window-dressing and were not employed in any meaningful way.

599. Upon information and belief, the Chain Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions. Instead, Chain Pharmacies put in place policies that required and rewarded speed and volume over the safety and care necessary to ensure that narcotics were distributed and sold lawfully. Defendants consistently put profits over safety in their distribution and sale of prescription opioids.

600. The Chain Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently

absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

**a. The Chain Pharmacies Have a Duty to Prevent Diversion**

601. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

602. First, under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding the State and the County, with more opioids than could be used for legitimate medical purposes, by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, and by failing to maintain effective controls against diversion from their retail stores, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

603. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

604. Third, distributors and chains pharmacies are required to register with the DEA to distribute and/or dispense controlled substances. See 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100; 28 C.F.R. § 1301.71. As registrants, Defendants were required to “maint[ain] . . . effective controls against diversion” and to “design and operate a system to disclose . . . suspicious orders of controlled substances.” 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. Defendants were further required to take steps to halt suspicious orders. Defendants violated their obligations under federal law.

605. Under the federal CSA and State controlled- substances laws, they likewise were required to design and operate effective systems to guard against diversion. See, e.g., 21 U.S.C. § 823; 28 C.F.R. § 1301.71. Federal regulations issued under the CSA also mandate that all registrants “design and operate a system to disclose to the registrant suspicious orders of

controlled substances.” 21 C.F.R. § 1301.74(b). These duties extend to Defendants as distributors and pharmacies. The Chain Pharmacies, like other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11.

606. Further, under the CSA, pharmacy registrants are required to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Thus, regardless of whether they are registrants, all dispensers must ensure that prescriptions of controlled substances are “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). The DEA has recognized that “as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion.”<sup>196</sup>

607. Under the CSA, the duty to prevent diversion lies with the Chain Pharmacies, not the individual pharmacist. As such, although it acts through its agents, the pharmacy is ultimately responsible to prevent diversion, as described above.<sup>197</sup> Further, the obligations under the

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<sup>196</sup> 2012 Dear Registrant letter to pharmacy registrants, <http://ppsconline.com/articles/2012/FLPDAC.pdf>

<sup>197</sup> *The Medicine Shoppe*; *Decision and Order*, 79 FR 59504, 59515 (DEA Oct. 2, 2014) (emphasis added); *see also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; *Decision and Order*, 77 FR 62316-01 (“When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge.”); *Top RX Pharmacy*; *Decision and Order*, 78 FR 26069, 62341 (DEA Oct. 12, 2012) (same); *cf. Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 82 (11th Cir. 2018) (revoking pharmacy registration for, *inter alia*, dispensing prescriptions that prescriptions presented various red flags, i.e., indicia that the prescriptions were not issued for a legitimate medical purpose without resolving red flags).

controlled-substances laws extend to any entity selling prescription opioids, whether it is the registration-holder or not.

608. Thus, in addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. The Chain Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions suggestive of potential diversion.

609. Fourth, Defendants also had duties under applicable state laws.

610. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants—which should include all distributors of controlled substances and pharmacies dispensing controlled substances—must adhere to the specific security, recordkeeping, monitoring, and reporting requirements that are designed to identify or prevent diversion. When the supply chain participants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

611. The CSA requires distributors and pharmacies, along with other participants in the supply chain of controlled substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of controlled substances like opioids; (b) register to distribute opioids; maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (d) identify suspicious orders of controlled substances and halt such sales.

612. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather “shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.” *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, “[o]rdering the same controlled substance from multiple distributors.”

613. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of

the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

614. Of course, due diligence efforts must be thorough: “the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor ‘inform’ the [DEA] about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed.”<sup>198</sup> Indeed, the DEA may revoke a distributor’s certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them “without performing adequate due diligence.”<sup>199</sup>

615. To comply with the law, wholesale distributors, including Defendants, must know their customers and the communities they serve. Each distributor must “perform due diligence on its customers” on an “ongoing [basis] throughout the course of a distributor’s relationship with its customer.” *Masters Pharms., Inc.*, 80 Fed. Reg. 55,418, 55,477 (DEA Sept. 15, 2015), petition for review denied, 861 F.3d 206 (D.C. Cir. 2017).

616. Pharmacy order data provides detailed insight into the volume, frequency, dose, and type of controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances and Schedule IV controlled substances (such as benzodiazepines), which are not reported to the DEA, but whose use with opioids can be a red flag of diversion.

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<sup>198</sup> *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at \*55477 (DEA Sept. 15, 2015).

<sup>199</sup> *Masters Pharmaceuticals*, 861 F.3d at 212. The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical’s certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA’s analysis and conclusion in the *Decision and Order*.



617. In addition to their duties as distributors, Defendants also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. Defendants had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

618. As acknowledged in an article CVS published in the New England Journal of Medicine, “[p]harmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular.” Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances - A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12., 2013, at 989-991. The DEA has identified “both pharmaceutical distributors and chain pharmacies as part of the problem” contributing to opioid abuse and related deaths. *Id.*

619. The Chain Pharmacies have a particular “advantage” in meeting their obligations under the CSA because these entities can use “aggregated information on all prescriptions filled at the chain” in order to examine “patterns” of opioids and other “high-risk drugs” and target “inappropriate prescribing.” *Id.* at 990. For example, a chain pharmacy should properly use its chainwide dispensing data to identify “high risk prescribers” by “benchmarking” prescription data based on “several parameters,” including “volume of prescriptions for high-risk drugs,” “the proportion of the prescriber’s prescriptions that were for such [high-risk] drugs, as compared with the volume and proportion for others in the same specialty and region,” cash payment, ages of patients, and the prescriber’s ratio of “prescriptions for noncontrolled substances with prescriptions for controlled substances.” *Id.* This “[a]nalysis of aggregated data” from chain pharmacies can “target patterns of abuse,” in the face of “the growing use of controlled

substances and resulting illnesses and deaths.” *Id.* Accordingly, as CVS touts, “innovative use of transparent data is only prudent.” *Id.*

620. As CVS counseled, Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify, report, and not fill prescriptions that seem indicative of diversion. That would include reviewing their own data, relying on their observations of prescribers, pharmacies, and customers, and following up on reports or concerns of potential diversion.

621. All suspicious conduct must be reported to relevant enforcement authorities. Further, Defendants must not fill or ship any suspicious prescription or order unless they have conducted an adequate investigation and determined that the prescription or order is not likely to be diverted into illegal channels.<sup>200</sup> Reasonably prudent distributors would not fall below this standard of care, and their failure to exercise appropriate controls foreseeably harms the public health and welfare.

622. In addition to their duties as distributors, Defendants also had a duty to design and implement systems to prevent diversion of controlled substances and to monitor and report suspicious activity in their retail pharmacy operations. Specifically, Defendants had a duty to analyze data and store-level information for known red flags such as (a) multiple prescriptions to the same patient using the same doctor; (b) multiple prescriptions by the same patient using different doctors; (c) prescriptions of unusual size and frequency for the same patient; (d) orders from out-of-state patients or prescribers; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with

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<sup>200</sup> See *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

opioids, like benzodiazepines, or prescription “cocktails”; (g) volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose.

623. According to law and industry standards, if a pharmacy finds evidence of prescription diversion, the Board of Pharmacy and DEA must be contacted.

624. As distributors and as pharmacies, Defendants have a duty, and are expected, to be vigilant in ensuring that controlled substances are delivered only for lawful purposes.

625. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors and pharmacies would not fall. Together, these laws and industry guidelines make clear that Defendants possess and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription opioids and of the risks and dangers of the diversion of prescription opioids when the supply chain is not properly controlled.

626. Further, these laws and industry guidelines make clear that Defendants have a responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

627. Reasonably prudent distributors and pharmacies would not fall below this standard of care, and their failure to exercise appropriate controls foreseeably harms the public health and welfare.

**b. Retail Pharmacies Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders.**

628. The regulations aim to create a “closed” system in order to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the

same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

629. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

630. Indeed, the DEA has repeatedly informed Defendants about their legal obligations, including obligations that were so obvious that they simply should not have required additional clarification.

631. For example, it is not an effective control against diversion to identify a suspicious order, ship it, and wait as long as weeks to report it to law enforcement, potentially allowing those pills to be diverted and abused in the meantime.

632. Defendants understood. As described below, at least Walgreens has itself acknowledged (internally) its understanding of the potential consequences of its failure to report and cease shipping suspicious orders.

633. In fact, trade organizations in which Defendants have actively participated have acknowledged that distributors have been responsible for reporting suspicious orders for more than 40 years. The National Association of Chain Drug Stores ("NACDS") is a national trade

association that represents traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four stores to national companies. Its members and/or affiliate members also include stakeholders such as manufacturers, other distributors, and other trade organizations as well. Most of the Defendants serve on the Board of Directors of NACDS. Chain Pharmacies have repeatedly chaired NACDS’s Board of Directors, which determines the “strategic plan and positions” of the organization. During the last 12 years, representatives of CVS, Rite Aid, and Walgreens have always held Board of Directors or officer seats.

634. The Healthcare Distribution Management Association (“HDMA,” now known as the Healthcare Distribution Alliance (“HDA”), and prior to 2000, known as the National Wholesale Druggists’ Association (“NWDA”)), is a national trade association representing distributors that has partnered with NACDS. The two groups viewed their relationship as a strategic “alliance.” CVS also has been a member of the HDA.

635. In 2006, the NACDS issued a “Model Compliance Manual” intended to “assist NACDS members” in developing their own compliance programs. The Model Compliance Manual notes that a retail pharmacy may:

“[G]enerate and review reports for its own purposes” and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste, and abuse, including:

- Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.
- Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.

- Geographic Zip Reports, which identify possible “doctor shopping” schemes or “script mills” by comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

636. In 2007 and 2008, the HDA, began developing “Industry Compliance Guidelines” (“ICG”) that aimed to outline certain “best practices” for distributors of controlled substances. As part of its development of the ICG, the HDA met with the DEA on at least three occasions. The HDMA also sought extensive input from its membership, as well as other groups such as the Pain Care Forum (mentioned *infra*). Internal discussions concerning the ICG further demonstrate the industry’s knowledge of what was expected of them. For example, when deciding whether or not the guidelines should permit a distributor to still ship a part of an order identified as suspicious, the HDMA noted that one potential downside of this approach was that “DEA correspondence/interpretation do not support this practice.”

637. The HDA released the ICG in 2008 and, in doing so, it emphasized that distributors were “[a]t the center of a sophisticated supply chain” and “uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”<sup>201</sup>

638. More recently, in in the appeal that arose from DEA’s enforcement action against wholesaler Masters Pharmaceuticals, Inc. for its distribution of opioids, the HDA and NACDS submitted a joint amicus brief regarding the legal duty of distributors that acknowledged that “HDMA and NACDS members” had a duty to prevent diversion. *See Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (D.C. Cir. April 4, 2016). As

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<sup>201</sup> Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B at 1).

described below, both the HDA and NACDS have both long taken the position that distributors have responsibilities to “prevent diversion of controlled prescription drugs” not only because they have statutory and regulatory obligations do so, but “as responsible members of society.”

639. The requirement to report suspicious orders at the time (not after the fact) has always been clear and Defendants themselves have acknowledged as much through their various trade groups and associations. As described above, correspondence between the NWDA and the DEA, as early as 1984, illustrates that the DEA provided clear guidance well before the opioid crisis was unleashed. For example, in one letter to the NWDA, DEA Section Chief Thomas Gitchel emphasized that “the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders,” noting “DEA has interpreted ‘orders’ to mean prior to shipment.” Consistent with that understanding, the NWDA’s 1984 Guidelines repeated the same directive.

640. In addition, the DEA, for example, in April 1987, sponsored a three-day “Controlled Substances Manufacturers and Wholesalers Seminar” that was attended by “over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers.”<sup>202</sup> According to the executive summary of the event, Ronald Buzzeo held a session on “excessive order monitoring programs,” wherein he explained:

[A]ny system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program.” Another area at issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company is still responsible under

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<sup>202</sup> US-DEA-00025657.

their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment.

641. The DEA also repeatedly reminded Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of internet pharmacies that arranged illicit sales of enormous volumes of opioids, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations.

642. Specifically, in August 2005, the DEA's Office of Diversion Control launched the "Distributor Initiative." The Distributor Initiative did not impose any new duties on distributors, but simply reminded them of their duties under existing law. The stated purpose of the program was to "[e]ducate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their [Automation of Reports and Consolidated Orders System ("ARCOS")] data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances."<sup>203</sup> The CSA requires that distributors (and manufacturers) report all transactions involving controlled substances to the United States Attorney General. This data is captured in ARCOS, the "automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions,"<sup>204</sup> described above, from which certain data was recently made public.

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<sup>203</sup> Thomas W. Prevoznik, Office of Diversion Control, Distributor Initiative presentation (Oct. 22, 2013), [https://www.deadiversion.usdoj.gov/mtgs/distributor/conf 2013/prevoznik.pdf](https://www.deadiversion.usdoj.gov/mtgs/distributor/conf%202013/prevoznik.pdf).

<sup>204</sup> U.S. Dept. of Justice, Drug Diversion Administration, Diversion Control Division website, <https://www.deadiversion.usdoj.gov/arcos/index.html>.



643. As part of the Distributor Initiative, the DEA gave several presentations to distributors both individually and through presentations and discussions at Defendants' trade groups meetings directly targeted at some of the red flags of diversion that the Defendants were obligated to consider and monitor as part of their requirements under the law.

644. The DEA has hosted many different conferences throughout the years, including Pharmacy Diversion Awareness Conferences, to provide registrants with updated information about diversion trends and their regulatory obligations. The DEA also frequently presented at various other conferences for registrants at the national, state, or local level.

645. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers' trustworthiness. As an example, the DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances"<sup>205</sup>

646. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances, including chain pharmacy distributors. The 2006 letter emphasized that distributors are:

one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of

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<sup>205</sup> U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration available at [https://www.deadiversion.usdoj.gov/mtgs/pharm\\_industry/14th\\_pharm/levinl\\_ques.pdf](https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, available at [https://www.mcguirewoods.com/news-resources/publications/lifesciences/product\\_diversion\\_beyond\\_pdma.pdf](https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.<sup>206</sup>

647. The letter also warned that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”<sup>207</sup>

648. The DEA sent a second letter to distributors on December 27, 2007. Again, the letter instructed that, as registered distributors of controlled substances, they must each abide by statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”<sup>208</sup> DEA’s letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting ARCOS data to the DEA).

649. In September 2007, the NACDS on behalf of its members, the Defendants, among others, also attended a DEA conference at which the DEA reminded registrants that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders. Walgreens, specifically, registered for the conference.

650. The DEA’s regulatory actions against the three largest wholesale distributors further underscore the fact that distributors such as Defendants were well aware of their legal obligations. There is a long history of enforcement actions against registrants for their

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<sup>206</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Off. of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (“2006 Rannazzisi Letter”).

<sup>207</sup> *Id.*

<sup>208</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (“2007 Rannazzisi Letter”); *see also* CVS-MDLT1000091513; WAGMDL00757797.

compliance failures. For example, in 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against three of Cardinal Health's distribution centers and on December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York. Similarly, on May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement ("AMA") with the DEA related to its failures in maintaining an adequate compliance program. Subsequently, in January 2017, McKesson entered into an Administrative Memorandum Agreement ("AMA") with the DEA wherein it agreed to pay a \$150 million civil penalty for, inter alia, failure to identify and report suspicious orders at several of its facilities.

651. The DEA has also repeatedly affirmed the obligations of pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.<sup>209</sup> The DEA, among others, also has provided extensive guidance to pharmacies on how to identify suspicious orders and other evidence of diversion.

652. DEA has repeatedly emphasized that retail pharmacies, such as Defendants, are required to implement systems that detect and prevent diversion and must monitor for and report red flags of diversion. When red flags appear, the pharmacy's "corresponding responsibility"

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<sup>209</sup> See, e.g., Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; 77 Fed. Reg. 62,316 (DEA Oct. 12, 2012) (decision and order); East Main Street Pharmacy, 75 Fed. Reg. 66,149 (DEA Oct. 27, 2010) (affirmance of suspension order); Holiday CVS, L.L.C. v. Holder, 839 F.Supp.2d 145 (D.D.C. 2012); Townwood Pharmacy; 63 Fed. Reg. 8,477 (DEA Feb. 19, 1998) (revocation of registration); Grider Drug 1 & Grider Drug 2; 77 Fed. Reg. 44,069 (DEA July 26, 2012) (decision and order); The Medicine Dropper; 76 Fed. Reg. 20,039 (DEA April 11, 2011) (revocation of registration); Medicine Shoppe-Jonesborough; 73 Fed. Reg. 363 (DEA Jan. 2, 2008) (revocation of registration).

under 21 C.F.R. § 1306.04(a) requires it either to take steps (and document those steps) to resolve the issues or else to refuse to fill prescriptions with unresolvable red flags.<sup>210</sup>

653. DEA has identified several types of “unresolvable red flags” which, when present in prescriptions presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include: a prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances; multiple prescriptions presented by the same practitioner to patients from the same address, prescribing the same controlled substances in each presented prescription; a high volume of patients presenting prescriptions and paying with cash; and, a prescription presented to by a customer who has traveled significant and unreasonable distances from their home to see a doctor and/or to fill the prescription at the pharmacy.

654. DEA guidance also instructs pharmacies to monitor for red flags that include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances as compared to other practitioners in the area, and (2) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Most of the time, these attributes are not difficult to detect and should be easily recognizable by Defendants’ diversion control systems.

655. The DEA has also explained these red flags in individual meetings with Defendants. For example, in December 2010, DEA hosted a meeting with CVS’s representatives and counsel and advised CVS of the “red flags . . . that a pharmacy should be familiar with in

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<sup>210</sup> *Pharmacy Doctors Enterprises, Inc. v. Drug Enf’t Admin.*, No. 18-11168, 2019 WL 4565481, at \*5 (11th Cir. Sept. 20, 2019).

order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose.”<sup>211</sup>

656. Examples of red flags that the DEA identified during its meeting with CVS include: many customers receiving the same combination of prescriptions (i.e., oxycodone and alprazolam); many customers receiving the same strength of controlled substances (i.e., 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam); many customers paying cash for their prescriptions; many customers with the same diagnosis codes written on their prescriptions (i.e., back pain, lower lumbar, neck pain, or knee pain); and individuals driving long distances to visit physicians and/or to fill prescriptions.<sup>212</sup>

657. Similarly, in 2011, the DEA took Walgreens “to the woodshed” over its dispensing cocktail drugs and opioids to questionable out of state customers, customers with the duplicate diagnoses, young people, and customers only paying cash. Many of these same red flags were highlighted in the 2009 Walgreens Order to Show Cause and resulting 2011 Memorandum of Agreement (“MOA”).

658. A more fulsome discussion of the various settlement agreements and enforcement actions against CVS, Walgreens, Rite Aid and Walmart is below.

659. As another example, in a 2016 presentation to the American Pharmacists Association, the DEA reiterated that retail pharmacies must watch for red flags such as: large numbers of customers who receive the same combination of prescriptions, receive the same strength of controlled substance prescription (often for the strongest dose), have prescriptions from the same prescriber, and have the same diagnosis code.

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<sup>211</sup> Declaration of Joe Rannazzisi in *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp.2d 145 (D.D.C. 2012).

<sup>212</sup> *Id.*

660. Many of these red flags are acknowledged in a “Stakeholders” memorandum created by many of the Chain Pharmacies, including CVS, Rite Aid, and Walgreens, others in the business of selling controlled substances for profit, like Purdue Pharma and Cardinal Health, and their trade organizations, including the HDMA and the NACDS.

**c. Defendants Were Uniquely Positioned to Guard Against Diversion.**

661. Not only do Chain Pharmacies often have firsthand knowledge of dispensing red flags – such as distant geographic location of doctors from the pharmacy or customer, lines of seemingly healthy patients, cash transactions, and other significant information – but they also have the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores. As with other distributors, these data points give the Chain Pharmacies insight into prescribing and dispensing conduct that enables them to prevent diversion and fulfil their obligations under the CSA.

662. Indeed, CVS Health president and CEO Larry Merlo has described the company as “America’s front door to health care with a presence in nearly 10,000 communities across the country,” which allowed it to “see firsthand the impact of the alarming and rapidly growing epidemic of opioid addiction and misuse.”<sup>213</sup>

663. As explained above, in addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. Specifically, the Chain Pharmacies had a duty to analyze data and the personal observations of their employees for known red flags such as (a)

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<sup>213</sup> See, e.g., David Salazar, *CVS Health Unveils New PBM, Pharmacy Efforts to Curb Opioid Abuse*, (Sept. 21, 2017), <https://drugstorenews.com/pharmacy/cvs-health-unveils-new-pbm-pharmacy-efforts-curb-opioid-abuse>

multiple prescriptions to the same patient using the same doctor; (b) multiple prescriptions by the same patient using different doctors; (c) prescriptions of unusual size and frequency for the same patient; (d) orders from out-of-state or distant patients or prescribers; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription “cocktails”; (g) volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose. The Chain Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, store, and chain level, and to refuse to fill and to report prescriptions that suggested potential diversion.

664. As described above and further below, the Chain Pharmacies also possessed sufficiently detailed and valuable information that other companies were willing to pay them for it. In 2010, for example, Walgreen’s fiscal year 2010 SEC Form 10-K disclosed that it recognizes “purchased prescription files” as “intangible assets” valued at \$749,000,000.<sup>214</sup> In addition, Walgreens’s own advertising has acknowledged that Walgreens has centralized data such that customers’ “complete prescription records” from Walgreens’s “thousands of locations nationwide” are “*instantly available*.”

665. Similarly, CVS’s Director of Managed Care Operations, Scott Tierney, testified that CVS’s data vendors included IMS Health, Verispan, and Wolters Kluwers and that CVS used the vendors for “analysis and aggregation of data” and “some consulting services.” He also testified that CVS would provide the vendors with “prescriber level data, drug level data, plan level data, [and] de-identified patient data.”<sup>215</sup>

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<sup>214</sup> [https://www.sec.gov/Archives/edgar/data/104207/000010420710000098/exhibit\\_13.htm](https://www.sec.gov/Archives/edgar/data/104207/000010420710000098/exhibit_13.htm)

<sup>215</sup> Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) \*245-46 (Feb. 22, 2011).

666. Each of the Chain Pharmacies had complete access to all prescription opioid dispensing data related to its pharmacies in the County, complete access to information revealing the doctors who prescribed the opioids dispensed in its pharmacies in and around the County, and complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the County. Each of the Chain Pharmacies likewise had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the County, complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the County, and complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the County. Further, each of the Chain Pharmacies had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by its pharmacies in and around the County and complete access to information revealing the size and frequency of prescriptions written by specific doctors across its pharmacies in and around the County.

667. Defendants, until March 2020, resisted producing their dispensing data in this MDL, and now seek to claw it back. Thus, while Defendants had access to data that would have demonstrated their knowledge of red flags and potential diversion, plaintiffs have not been able to access that data to fully analyze both what Defendants knew, or should have known, and the impact that they could have had in preventing diversion in the County.

**d. Defendants were Uniquely Positioned to Guard Against Diversion.**

668. As described further below, the Chain Pharmacies failed to fulfill their legal duties and instead, routinely distributed and/or dispensed controlled substances while ignoring



red flags of diversion and abuse. The unlawful conduct by these Defendants is a substantial cause for the volume of prescription opioids and the public nuisance plaguing the County.

**i. CVS**

669. CVS distribution centers, in tandem with outside wholesalers, such as Cardinal, supplied opioids to CVS pharmacy stores until October 2014. CVS self-distributed hydrocodone and hydrocodone combination products to its own stores, of which CVS had approximately 6,000 by 2006 and 9,700 by 2014. Hydrocodone (HCP) was previously a Schedule II opioid, but rescheduled to FDA Schedule II status October 6, 2014. CVS ceased self-distributing hydrocodone the same day the rescheduling took effect.

670. CVS pharmacies nationwide placed orders with CVS distribution centers through CVS's central mainframe computer ordering system.

671. Before 2009, CVS, which stocked and sold opioids at more than 9,000 stores across the country, lacked any meaningful suspicious order monitoring ("SOM"). Instead, CVS relied on the gut instincts of pickers and packers of the drugs in the distribution center -- workers responsible for pulling items off distribution shelves for delivery to pharmacy stores -- to identify "really big" orders that they believed were simply too large. This, of course, was not an effective SOM system.

672. Moreover, CVS lacked a training program to train its Pickers and Packers how to identify unusual orders of size, frequency, or pattern. CVS also did not have any written policies, procedures, or protocols with respect to the Pickers' and Packers' obligations until August, 2013. And, there were no formal job requirements to be employed as a Picker and Packer.

673. In 2007, with the help of an outside consultant, CVS began work on a Standard Operating Procedure Manual ("SOP") that was intended to cover all facets of DEA controlled substances compliance, including suspicious order monitoring. However, by the Summer of

2010, neither the final manual nor the SOM section was complete: Internal documents from that time acknowledge that CVS was “still in the process of writing the suspicious order monitoring section of this standard operating procedure.” In fact, the section of the Standard Operating procedures for Suspicious Order Monitoring states “BEING DEVELOPED AND WRITTEN.”

674. Drafts of the SOP Manual, meanwhile, show CVS understood, or should have understood, that this was unacceptable. The draft manual provides that: “CVS is responsible for ensuring compliance with DEA regulatory requirements, and that responsibility cannot be abdicated or transferred to anyone else.” Despite this acknowledgement, when the first version of the SOP Manual was issued in December 2007 and for multiple revisions thereafter, the SOM section still remained incomplete. It was not completed until August of 2010. Completion of the Manual in 2010 did not equate to compliance, however.

675. As John Mortelliti, CVS’s Director of Loss Prevention, wrote in November 2009, this had become “a big issue with CVS and the DEA,” and he was “trying to get a rough draft SOM SOP” before a DEA meeting. CVS only incorporated the final missing SOMs section because of the need to fulfill an apparent promise to provide it to the DEA.

676. CVS Indiana was audited and investigated by the DEA for its distribution practices on August 24, 2010. The day after the DEA’s audit of CVS’s distribution practices began, on August 25, 2010, CVS Pharmacy, Inc. sent a new SOP, which included for the very first time a policy on SOM. CVS Pharmacy, Inc. internally posted the SOP be posted at 1:35 pm on August 26, 2010. The document was hastily put together. The SOM section was actually cut and pasted into the SOP twice.

677. On September 1, 2010, John Mortelliti sent an e-mail to Terrance Dugger who was present during the DEA audit. The subject of the e-mail and the attachment is “DEA

Speaking Points”, the importance was listed as high. He writes: “Terrence, This is for the DEA. The corrections listed below have been updated. It is ok to review this with the agents.”

678. Mr. Mortelitti then sent the same presentation on the same day to another group of CVS employees writing: “These are the final approved speaking points for the DEA agents if they come to one of your facilities and question suspicious monitoring. It is ok to share this document. Please be sure your team understands it before presenting so it doesn’t look like a prop instead of a tool.” The presentation sent by Mr. Mortelitti to be shared with the DEA was not correct and was not the procedure being used by CVS.

679. CVS had a “CVS DEA compliance coordinator” in name only. A CVS employee who held the position from 2008 to 2014 said that her title was only “for reference in SOPs,” and not her real job. For “personnel purposes,” she was never considered the CVS DEA compliance coordinator. Moreover, she had nothing to do with suspicious order monitoring, other than, as she stated, “updating the SOP with what was provided for the program.”

680. It was only in 2009 that CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. The automated program was delivered by an outside vendor to CVS in December of 2008.

681. CVS called the output of the flagged orders an Item Review Report (“IRR”).

682. The SOM algorithm delivered in December 2008 was designed to “pend” (or identify) an order with a score of 0.15 or higher as potentially suspicious. The higher the score the more likely the order was potentially suspicious. In July, 2009 CVS reported to the algorithm designer that the SOM model was pending a large number of orders that CVS believed were “not suspicious on their face” and it requested that the model be changed. As a result, revised coefficients for the algorithm were delivered to CVS on August 27, 2009 and the pend score of .15

remained the same. Between June, 2010 and August, 2010 Mortelliti adjusted the IRR pend score from .15 to .65. The higher the score, the less sensitive the model, flagging fewer potentially suspicious orders for investigation. On February 8, 2011, a completely retuned SOM algorithm with another set of co-efficients was again delivered to CVS by the algorithm designer. The February, 2011 changes returned the pend score to .15. CVS again changed the pend score to .65.

683. IRRs were the primary SOM process. A CVS corporate representative explained, on behalf of the company, “for the most part,” if an order was not flagged as suspicious under the IRR system, there would be no due diligence of that order. Yet, CVS neglected to provide written instructions to its employees for how to perform that critical review until February 29, 2012.

684. CVS’s IRR system was deficient and failed in many respects to meet CVS’s obligations as a distributor.

685. CVS also learned in 2010 that its SOM algorithm was not working properly because it monitored by drug, not active ingredient, meaning that changes in a drug’s description or name caused historical data to be lost. Thus, the system was unable to determine that orders for these drugs exceeded or diverged from prior volumes or patterns.

686. CVS’s SOMs algorithm also failed to consider outside vendors orders. In other words, CVS’s SOM system would not track how many opioids CVS was ordering from third party distributors such as Cardinal when evaluating whether to distribute opioids to one of its pharmacies. CVS knew this was a problem, as a “[s]tore may order a little from both the OV [outside vendor] and DC [CVS distribution center] to stay under the radar.” It also knew that excluding outside vendor data meant CVS “may ship a potentially reportable suspicious order

from [its] DC.” Stores, including one that had a “68,000 hydrocodone pill loss,” could also place telephone orders to outside vendors, into which there was “no visibility . . . until a later time.” This deficiency is particularly glaring because, at a corporate level, CVS had full access to the orders its pharmacies placed to outside vendors.

687. Acknowledging the ineffectiveness and deficiencies within its SOM system, CVS hired new consultants in 2012 to troubleshoot its existing SOM systems for the purpose of either fixing the deficient system or developing a new SOM system so as to attempt to become compliant with the law.

688. Still, as late as July 2013, internal e-mail reflects that CVS’s primary tool for investigating suspicious orders relied on data that was months or even years old and made any analysis, “for the most part, irrelevant and pointless.”

689. Not until mid to late 2014 did CVS fully implement anew SOM system. Even still, CVS encountered problems in evaluating suspicious orders for opioids and its SOMS was entirely lacking. More specifically, CVS implemented a new SOM system in the Indianapolis distribution system in March of 2014. The deployment was further delayed due to system data feed issues that created inaccuracies in the SOM historical data. A risk analysis of the new system was conducted in June of 2014. The risk level was determined to be high for the SOM system in the following categories covering seemingly every aspect of its operation: inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; inconsistency in documenting due diligence investigations of suspicious orders; lack of engagement by the Management Team; lack of communication between the SOM Management Team and SOM Analysts; lack of resources to handle the rollout of the new SOM system to all distribution centers; lack of clarity in how the new SOM system is identifying suspicious orders.

Essentially, the key components of a compliant and effective SOMS system. That same year, CVS stopped distributing opioids at the wholesale level.

690. Meanwhile, on August 5, 2013 the DEA began another audit and investigation of the CVS distribution center in Indiana. CVS's own documents acknowledge that the DEA's investigation was focused on its failure to maintain a SOM program for controlled substances.

691. In response to queries from the DEA, CVS wrote a letter to the DEA revealing that it had only stopped seven suspicious orders across the entire country. Right before sending the letter the author, Mark Nicastro, head of the CVS distribution center in Indiana, conceded internally that "I wish I had stopped more orders that went back further." Sadly, while Mr. Nicastro was writing the letter on CVS's behalf to the DEA, he couldn't even locate the SOP for the SOM writing to Pam Hinkle, "For the life of me I can't find the SOP for SOM. Can you send me an electronic copy please? I have been on the logistics website, looked through hundreds of e-mails, nothing. I'm surprised it is not on the website." Ms. Hinkle, Sr. Manager for Logistics, quality and Compliance for CVS, responds that she too is unsure of the final version of the SOP SOM. CVS sent the wrong version of the SOP SOM to the DEA.

692. In May of 2014, CVS had a closing meeting with the DEA related to the distribution center audit. According to handwritten notes from a CVS employee who attended the meeting, the "most serious" violation is "failure to design" a SOM system. An internal CVS e-mail summarizing the meeting made a similar statement: DEA determined that CVS "faile[d] to maintain an SOM program." The head of CVS's distribution center in Indiana described Betsy Ferguson's, CVS's in-house counsel, confrontation with the DEA during the meeting writing: "Dan [DEA Agent] finally pushed Betsy's button and the gloves came off Betsy made it very clear that a letter of admonishment was one thing. Anything other than that and she wanted an

opportunity to do a presentation to his boss and her boss about what we do with SOM. Anything more than a letter and we would meet in D.C. in courts just like Walgreens did.”

693. The DEA issued its closing letter concluding that CVS failed to design and maintain a system to detect suspicious and report suspicious orders for Schedule II-V Controlled Substances as required by Title 21 United States Code (USC) 821, Title 21 USC 823(e)(1), and Title 21 Code of Federal Regulations (CFR) 1301.74(b) in violation of Title 21 USC 842(a)(5).

694. All orders that appeared on the IRR required a thorough due diligence investigation, but only a very small percentage were subjected to appropriate due diligence. From early/mid-2009 through early 2011, one employee, Mortelliti, the Director of Loss Prevention, “was taking the first pass through the IRR himself.” According to CVS’s corporate witness, “Mr. Mortelliti’s practice would have been to review the report on a daily basis and determine whether items on the report warranted further review and due diligence and conduct review and due diligence as he deemed appropriate.” At select times in 2013, CVS had only one full-time employee in the position of “SOM analyst” reviewing all potentially suspicious orders for every pharmacy in the country. The SOM system would identify orders as potentially suspicious based on a number of factors and “pend” the order. Even though the orders had been identified as potentially suspicious, the CVS SOM analysts would conduct an “in depth” dive on only select orders. In fact, the SOM program could identify as many as 1,000 suspicious orders a day; the CVS employee would only do a “deep dive” on one to six orders per day.

695. Even as late as 2012, CVS’s SOM was clearly little more than window dressing. For example, CVS’s own SOMs policy specified that if multiple orders for the same store are flagged during the same month, all orders after the first order will not be investigated and will be automatically released based on the release of the first order.

696. As noted above, as of November 21, 2013, CVS had only reported seven suspicious orders to the DEA across all of its distribution centers and pharmacies in the United States. The first suspicious order CVS ever reported was on February 29, 2012. Upon information and belief, CVS reported no suspicious orders in this State.

697. CVS's collaboration with Cardinal distributors went from lobbying to actually preventing adequate due diligence investigations of suspicious opioid orders. CVS knew that Cardinal and McKesson have independent due diligence obligations under the CSA to monitor all sales of controlled substances for orders which deviate in size, pattern, or frequency. CVS understood that, to do so effectively, Cardinal and McKesson would require access to its dispensing information. CVS did not provide dispensing information to Cardinal or McKesson. In an email from Paul Farley to Michael Mone, both Cardinal employees, Farley wrote, "I spoke with Brian Whalen at CVS a couple of times this morning... They will not provide the doctor or patient information you requested unless it is requested by the DEA. He was quite adamant about this." CVS prevented Cardinal and McKesson from obtaining access to critical dispensing information for its pharmacies to enable Cardinal and McKesson to conduct adequate due diligence of its pharmacies. Prior to 2013, Cardinal and McKesson did not investigate CVS by calling its pharmacists or visiting CVS stores as they did with other pharmacies. Instead, distributors were instructed to contact CVS's loss prevention offices at corporate headquarters to inquire about suspicious orders, ensuring that any investigation into CVS ordering of opioids was conducted by CVS alone.

698. As a result, CVS controlled all "due diligence investigations" of its opioid orders.

699. CVS also prevented its distributors from independently determining the appropriate order thresholds for opioids at CVS stores. CVS contractually protected its right to



establish and change its threshold requirement for Schedule II controlled substances with Cardinal. The agreement expressly states that CVS has the discretion under the contract to set its threshold quantities for controlled substances at any level CVS deems appropriate:

CVS requires the ability to adjust (up or down) the quantity of product our stores receive, this adjustment will be made on an NDC by NDC basis and will include a Threshold Quantity and an Adjustment Percentage. Both the Threshold Quantity and Adjustment Percentage can be set to any value CVS deems appropriate.

700. In 2015, CVS Health Corp. acquired Omnicare, which provides pharmacy-related services to long-term care facilities and other health care facilities throughout the United States. Omnicare dispenses controlled substances under Certificates of Registration issued by the DEA.

701. When CVS acquired Omnicare, CVS was fully aware the DEA had previously investigated Omnicare for “alleged errors and deficiencies in paperwork requirements for controlled-substances dispensing at several of the company’s pharmacies in Ohio.”<sup>216</sup> Omnicare publicly acknowledged the DEA’s investigation in its 2010 SEC filings, which Omnicare later settled in 2012. CVS was also aware the DEA had previously investigated Omnicare in 2007 for countrywide violations of the CSA that also led to a settlement with the Agency. The DEA determined that between 2007 and 2012 Omnicare:

- Dispensed controlled substances to residents of long-term care facilities without valid prescriptions, including but not limited to dispensing controlled substances pursuant to written orders that did not contain all of the elements of a valid prescription including the signature of the prescribing practitioner, in violation of 21 U.S.C. §§ 353(b), 829 and 842(a)(1) and 21 C.F.R. §§ 1306.11 and 1306.21;
- Failed to comply with all of the elements of the emergency oral prescription requirements set forth in 21 C.F.R. § 1306.11(d), including but not limited to dispensing Schedule II controlled substances or authorizing facility staff to remove Schedule II controlled substances from emergency supplies located at long-term care facilities without oral authorizations directly from prescribing practitioners and failing to notify the nearest

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<sup>216</sup> “Omnicare Faces Federal Probe, Wall Street Journal, 28 Oct. 2010.

office of DEA if the prescribing individual practitioner failed to deliver a written prescription to the pharmacy within seven days, in violations of 21 U.S.C §§ 8429(a)(1) and (a)(5);

- Dispensed controlled substances to residents of long-term care facilities without prescriptions meeting the requirements of 21 C.F.R. §§ 1306.05(a) and 1306.11(f), including but not limited to dispensing controlled substances pursuant to pre-populated prescriptions prepared by the pharmacies and dispensing controlled substances pursuant to written orders that lacked one or more of the following: the signature of the practitioner, the date of issuance, the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, or the name, address and DEA registration number of the practitioner, in violation of 21 U.S.C § 842(a)(1); and,
- Not maintaining records of prescriptions for controlled substances listed in Schedule II in compliance with 21 C.F.R. part 1304, in violation of 21 U.S.C. § 842(a)(5).<sup>217</sup>

702. In 2012, Omnicare paid \$50 million to resolve these allegations.

703. Since its acquisition by CVS, Omnicare has continued to violate the CSA. In May 2020, Omnicare settled additional charges made by the DEA paying \$15.3 million. The DEA found that Omnicare again violated the CSA:

in its handling of emergency prescriptions, its controls over the emergency kits, and its processing of written prescriptions that had missing elements. The federal investigation found that Omnicare failed to control emergency kits by improperly permitting long-term care facilities to remove opioids and other controlled substances from emergency kits days before doctors provided a valid prescription. The investigation also revealed that Omnicare had repeated failures in its documentation and reporting of oral emergency prescriptions of Schedule II controlled substances.<sup>218</sup>

704. Many of the recent allegations made by the DEA repeat those violations Omnicare engaged in before 2012. The Acting Administrator of the DEA stated, “Omnicare failed in its responsibility to ensure proper controls of medications used to treat some of the most vulnerable among us.”<sup>219</sup> CVS, fully aware of the past compliance failures and fully aware of the

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<sup>217</sup> Settlement Agreement between DEA and Omnicare dated May 10, 2012.

<sup>218</sup> Press Release May 13, 2020, “Omnicare, Inc. agrees to pay more than \$15 million to resolve allegations it improperly dispensed narcotics at long term care facilities.”

<sup>219</sup> *Id.*

enormous danger posed to the public from the diversion of opioids, failed to properly monitor and create a corporate system through which it could ensure that its subsidiaries complied with the CSA.

705. As a vertically integrated distributor and dispenser of prescription opioids, CVS knew or should have known that an excessive volume of pills was being sold into Plaintiff's Communities and ultimately, onto its streets. CVS's activities as a distributor and a seller or dispenser of opioids are inextricably linked.

706. CVS violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

707. The sheer volume of prescription opioids distributed to and dispensed by CVS pharmacies in and around the County is indicative of potential diversion and required appropriate due diligence.

708. CVS funneled far more opioids into Plaintiff's Communities, and out of its pharmacy doors, than could have been expected to serve legitimate medical use, and ignored other red flags of diversion, including but not limited to suspicious orders.

709. It cannot be disputed that CVS, was aware of the suspicious orders that flowed from its distribution facilities into its own stores. CVS simply refused to identify, investigate, and report suspicious orders even though CVS knew, or should have been fully aware, that opioids it distributed and sold were likely to be diverted. Conversely, CVS failed to report suspicious orders, failed to meaningfully investigate or reject suspicious orders, and failed to prevent diversion, or otherwise control the supply of opioids.

710. Upon information and belief, CVS failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

711. CVS was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

712. Given CVS's retail pharmacy operations, in addition to its role as a wholesale distributor, CVS knew or reasonably should have known about the disproportionate flow of opioids and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

713. In addition, CVS knew, or deliberately turned a blind eye, to its pharmacies' role in diversion of dangerous drugs. At the pharmacy level, discovery will reveal that CVS knew or should have known that its pharmacies in Plaintiff's Communities, and the surrounding area, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted

or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. CVS had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

714. Failures regarding dispensing in CVS's Florida stores also allowed diverted opioids to be funneled into the County. And, CVS saw huge increases in the quantity of oxycodone it dispensed in Florida from 2006 to 2010. For example, starting with an already high baseline, a single CVS ordered approximately four times the amount of oxycodone a typical pharmacy orders in one year in 2006. By 2010, the same pharmacy's 10-month history showed quantities more than thirty times the amount of oxycodone a typical pharmacy orders in one year, and the pharmacy's supervisor could not explain why the volume was so high. During that time, Cardinal was the pharmacy's main distributor, and two of CVS's Florida pharmacies were among Cardinal's top four retail pharmacy customers, dispensing a staggering amount of oxycodone compared to Cardinal's other Florida customers. Interviews with employees of these pharmacies revealed that they routinely observed red flags and obvious signs that they were filling illegitimate prescriptions. One set a daily limit of oxycodone 30mg prescriptions the pharmacy would fill each day, basing the limit on the amount in stock that day, so as to ensure that the "real pain patients" could get their prescriptions filled. The pharmacy usually reached its limit by lunchtime each day, and at times within 30 minutes of opening. Customers, aware that prescriptions were first come, first served, would line up outside the store as early as 7:45 AM.

An employee acting as “bouncer” included escorting off the premises customers who were “hooked” on opioids and became belligerent if their prescriptions were refused among his job duties. Although CVS had in place dispensing guidelines for controlled substances prescriptions, these guidelines were not followed at these stores. Rather, they dispensed controlled substances prescriptions despite clear red flags.

715. Because of its vertically integrated structure, CVS has access to complete information regarding red flags of diversion across its pharmacies in and around the County, but CVS chose not to utilize this information and failed to effectively prevent diversion.

716. By 2009, CVS Pharmacy, Inc. owned and/or operated more than 9,000 pharmacies in the United States. According to its website, CVS now has more than 9,900 retail locations. At all times relevant herein, CVS pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances otherwise known as opiate narcotics or opioids.

717. “CVS Corporation,” not any individual CVS store, is the DEA registrant for each of CVS’s pharmacies across the country. CVS renews the DEA licenses for its pharmacies through a “Registration Chain Renewal.” From October 2013 through December 2016, CVS headquarters paid more than \$5 million to renew the licenses for 7,597 CVS locations

718. As described above, until October 6, 2014, CVS pharmacies ordered and were supplied FDA Schedule III hydrocodone combination products (HCPs) from a combination of outside vendors and CVS distribution centers. CVS pharmacies also received Schedule II opioids from outside vendors, with Cardinal acting as its exclusive outside supplier for the entire period for which ARCOS is available. Upon information and belief, McKesson also acts or has acted as an outside vendor for CVS.

719. CVS Pharmacy, Inc. instituted, set-up, ran, directed, and staffed with its own employees most of the SOM functions for its pharmacy stores.

720. CVS also lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion, even as they evolved over time. Not until 2012 did CVS create guidelines explaining in more detail the “red flags” or cautionary signals that CVS pharmacists should be on the lookout for to prevent diversion and to uphold their corresponding responsibilities to ensure that all dispensed controlled substances are issued for a legitimate medical purpose.

721. Even so, CVS’s conduct, and the volume it dispensed in the County thereafter indicates that its policies were not applied. In addition, as discussed further below CVS had performance metrics in place that pressured pharmacists to put profits ahead of safety.

722. CVS failed to use data held at the corporate level to assist pharmacists in evaluating red flags of diversion. CVS’s later dispensing policies and procedures make clear that for most of the time CVS has been engaged in the sale and dispensing of opioids, there was no meaningful integration of data and information that was within the possession and control of CVS corporate personnel.

723. Notably, with respect to CVS’s suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that *litigation*. See Opinion and Order [Denying CVS’s Motion for Summary Judgment], MDL No. 2804, Doc.3099 (N.D. Ohio Jan. 27, 2020).

## **ii. Walgreens**

724. Acting as both a distributor and a retail pharmacy chain, Walgreens also self-distributed opioids to its own individual Walgreens pharmacies. Although Walgreens had

visibility into red flags of diversion due to its vertically integrated distribution and dispensing practices, it failed to take these factors into account in its SOM program during the vast majority of the time it was distributing prescription opioids. Moreover, its program was wholly inadequate and did not fulfill its duties to prevent diversion. Likewise, Walgreens also failed to maintain effective controls against diversion from its pharmacy stores.

725. Though Walgreens had access to significant information about red flags due to its vertical integration with its stores, Walgreens failed to use available information to monitor and effectively prevent diversion.

726. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulas to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

727. Walgreens used two different formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then deemed certain orders which were greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period. Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.

728. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient," via a May 2006 Letter of Admonition. The



Letter cited Walgreens for controlled substances violations at its Perrysburg, Ohio Distribution Center, but highlighted problems that went far beyond that particular facility.

729. The DEA also reminded Walgreens that its suspicious ordering “formula should be based on (size, pattern, frequency),” though Walgreens failed to even examine anything other than the size of an order. When Walgreens did update its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use another “three times” formula.

730. Even with its ample threshold, each Walgreens Suspicious Control Drug Order report could be thousands of pages or more in length.

731. Walgreens did not perform any due diligence on the thousands of orders identified as “suspicious” on the Suspicious Control Drug Order reports, but instead shipped the orders without review.

732. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until after the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening the regulatory requirement that suspicious orders be reported when discovered. 21 C.F.R. 1301.74(b). In some instances, months may have elapsed between an order’s shipment and its subsequent reporting to the DEA, given the requirement, described above, of two consecutive months of exceeding the three times multiplier to trigger reporting.

733. In September 2012, the DEA issued an immediate suspension order (“ISO”) for one of Walgreens’s three Schedule II distribution centers, finding Walgreens’s distribution practices constituted an “imminent danger to the public health and safety” and were “inconsistent with the public interest.” The DEA further found that Walgreens’s Jupiter distribution center

failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates. There, the DEA stated: “Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies.”

734. In the ISO, the DEA also specifically considered the Suspicious Control Drug Order reports and made the following further findings of fact and conclusions of law regarding the reports and Walgreens’s suspicious order monitoring system—applicable across Walgreens’s operations:

- “[Walgreens’s] practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled ‘Suspicious Control Drug Orders.’”
- “[The Suspicious Control Drug] reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title [Walgreens] attached to these reports.”
- Upon review of an example of the Suspicious Control Drug Order report for December 2011, “[Walgreens’s] suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico.”
- Finding that the reports failed to appropriately consider the population and area being served by the pharmacy: “This report from the Jupiter [Florida] Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the

pharmacy's location, the population it serves, or the number of other pharmacies in the area.”

- “As made clear in 21 CFR§ 1301.74(b), Southwood, and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported as discovered, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place before the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded.”
- “DEA's investigation of [Walgreens] ... revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b).”
- “. . . DEA investigation of [Walgreens's] distribution practices and policies ... demonstrates that [Walgreens] has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. 55 823(b)(1 and (e)(1). [Walgreens] failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. . . . [Walgreens has not] recognized and adequately reformed the systemic shortcomings discussed herein.”
- “[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [for which DEA suspended Walgreens' dispensing registration].”

735. Walgreens knew its procedures were inadequate well before the 2012 ISO issued.

In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that “[t]he submission of a monthly printout of after-the-fact sales does not relieve the registrant

of the responsibility of reporting excessive or suspicious orders.” The DEA further advised Walgreens that, while “[a]n electronic data system may provide the means and mechanism for complying with the regulations...the system is not complete until the data is carefully reviewed and monitored by the registrant.”

736. Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before shipment. One of the managers for Walgreens’s Pharmaceutical Integrity (“RX Integrity”) Department stated that, when he was with the Loss Prevention Department, he “basically burned the data on a CD and sent it off. I didn’t dive into each individual report or CD” and that he “would look at it briefly, but just to see if the data transferred to the CD, but that’s about the extent.”<sup>220</sup> In an errata submitted in connection with a deposition in the MDL, Walgreens acknowledged that it “is currently unaware of due diligence that was performed based on orders being flagged . . .”<sup>221</sup>

737. As described above, in May 2006, the DEA told Walgreens again that the formula Walgreens was using to identify suspicious orders for the Suspicious Control Drug Order reports was “insufficient” and “inadequate.”

738. Moreover, in September 2007, three Walgreens’s senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control’s 13th Pharmaceutical Industry Conference in Houston, Texas. Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this

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<sup>220</sup> E Stahmann Dep. at 287: 16-23.

<sup>221</sup> See E. Bratton 30(b)(6) Dep. Erratum No. 3.

Conference relating to suspicious orders, which included the reminder that the CSA “requirement is to report suspicious orders, not suspicious sales after the fact.” Participant notes from this meeting indicate that Mr. Mapes advised the audience not to “confuse suspicious order report with an excessive purchase report. They are two different things.”

739. Similarly, handwritten notes on an internal document from July 2008 state that “DEA really wants us to validate orders and only report true suspicious orders or what was done to approve orders.” They go on to state that “[j]ust reporting these orders is not good enough – need to document what happened.”

740. Additionally, in November 2012, the Walgreens’s Divisional Vice President of Pharmacy Services reported to Kermit Crawford, Walgreens’s President of Pharmacy, Health and Wellness, his notes from meeting with the DEA about reporting suspicious orders, which included the note, “[i]f suspicious - you don't ship.”

741. In a December 2008 Internal Audit of its Perrysburg Distribution Center, Walgreens admitted to systemic and longstanding failures in the systems surrounding DEA compliance:

In our opinion internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions. Specifically, our review found four issues previously cited in the DEA’s May 2006 inspection report that are still open. In addition, four issues noted in our previous audit (report dated July 2005) remain unremediated. Areas requiring the greatest level of improvement are as follows:

[Distribution Center-]-wide:

- pseudoephedrine reporting requirements and inventory maintenance
- suspicious controlled drug order processing and reporting

- controlled drug reporting, specifically receiving record information
- lack of formalized CII controlled substance policies and procedures.

742. The Internal Audit goes on to state that “Walgreens is required to have a process to disclose to the DEA any suspicious orders of controlled substances that deviate from the normal size, pattern, and frequency. Any orders that are deemed to be suspicious are required to be reported to the DEA upon discovery.” It also notes that while “Walgreens produces monthly Suspicious Controlled Drug Orders report,” the audit team recommended discussions continue across multiple departments within Walgreens regarding “reporting suspicious control drug orders” and an “Updated Suspicious Control Drug Order Identification Methodology,” with an “Estimated Completion Date for the New Reporting” of “June 30 2009.” In this respect, too, it makes clear that the failures described are systemic. The audit also underlined Walgreens’s lack of urgency in addressing the problems, indicating that the next “Cross-Functional Meeting” to address the “Updated Suspicious Controlled Drug Order Identification Methodology” would not occur for more than five months, at the end of May 2009.

743. Walgreens nominally employed additional procedures within its distribution centers; however, these systems did not address the failings of the Suspicious Control Drug Order reports. These distribution center systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens admits that its Distribution Centers are “more akin to supply warehouses,” are “not designed to be a backstop to pharmacists,” and that they are not well “equipped to ensure compliance” or to “assist in combatting controlled substance abuse,” and “do not have the ability to detect trends in local markets.”

744. The Distribution Center (“DC”) level procedures are documented in a 2006 Questionable Order Quantity policy, which had two facets: First, it instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. The policy did not mention reporting suspicious orders until 2010, when it was updated to state that the Corporate Office Internal Audit Department would handle suspicious store orders and inquiries. There is no evidence that the Internal Audit department had any involvement in reporting suspicious orders.

745. The second aspect of this DC level procedures required “pickers,” the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for “questionable” orders while picking.

746. The only review of the orders identified by the DC level procedures was calling the pharmacy to make sure the order had not been entered in error. Walgreens admitted this procedure was not intended to detect suspicious orders.

747. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens’s distribution-center level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being “suspicious” on the Suspicious Control Drug Order reports.

748. Walgreens’s documents effectively acknowledge that these were not true anti-diversion measures, and it recognized internally that it did not begin creating a suspicious order monitoring [“SOM”] system until March 2008. Specifically, in March 2008, Walgreens finally formed a five department “team” to “begin creating” a SOM program. The new SOM program was not piloted until more than a year later, in August 2009, and even then, the pilot included orders from just seven stores. Not until September 2010 would the program, implemented in

pieces and phases, be rolled out chain-wide, and from that point it took several more years to fully implement.

749. Through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens's "three times" test, showing that Walgreens's post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

750. Walgreens did not prioritize compliance when instituting its SOM system. MDL testimony from the Senior Director of the Walgreen's Pharmaceutical Integrity Department, which is charged with supervising Walgreens's SOM system, revealed that even as late as 2012, 2013, and 2014, Walgreens's viewed the SOM system as an inventory control mechanism rather than as a compliance control mechanism:

Q: Now, Walgreens's system, similar to my alarm, is there to detect a potential red flag. Would you agree with that?

A: It was put in place to ensure that the stores had the proper quantities. Not necessarily to . . . detect a red flag. The whole idea was to make sure that the stores were getting the quantities that they needed based on their peer group.

751. Perhaps because keeping supply moving, as opposed to preventing diversion, was Walgreens's primary focus, the SOM program Walgreens slowly developed had significant gaps or loopholes. For example, for the first few years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Cardinal and AmerisourceBergen, allowing stores to order opioids from Walgreens distribution centers and from Cardinal and AmerisourceBergen, effectively permitting double dipping. It also did not prevent stores from placing an order to an outside vendor if the store attempted to place the order to a Walgreens DC, but was rejected by the new SOM system.



752. The new SOM-lite system also allowed Walgreens's stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into SOM analytics. Additionally, stores could also place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days and outside of the SOM analysis and limits. Walgreens could even remove a store entirely from SOM review.

753. Further, although the new SOM algorithm identified more than 389 pages of suspicious orders per week as of August 2010, it failed to identify all the orders that Walgreens had marked as suspicious under its "three times" formulas and previously listed on its Suspicious Control Drug Order reports and submitted to the DEA "on a monthly basis." This "discrepancy" prompted an internal email from an employee in Walgreens's Loss Prevention Department, to Walgreens's Vice President, Distribution Centers and Logistics, suggesting that "the new system should be tested further and enhanced to provide broader coverage of controlled substance activity. The same e-mail stated that "we are not equipped to handle the 389+ pages of ADR4 [suspicious order monitoring] data which are compiled nationwide each week," and asked if his department had "a resource available" to assist. An email in response "recall[ed] the old paper report as being inches thick" and an instruction "in 1985 not to review or contact anyone on the data," and inquired, among other things, "[w]ho from your group has been reviewing the data collected for the past twenty-five years?" and "[a]t present is anyone doing any review on what would be considered suspicious quantities that are physically ordered and are releasing to stores?"

754. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens's new SOM system were reduced to the store limit and shipped out. These orders

were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens's policy of reducing and then filling and shipping suspicious orders without reporting them violated the law:

This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to orders, not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood*, is “to provide investigators in the field with information regarding potential illegal activity in an expeditious manner.” 72 FR at 36501.

755. Walgreens's post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as 20,699 orders for controlled substances were “marked suspicious” by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best. Meanwhile, Walgreens failed to adequately staff the program and to train its employees regarding its requirements.

756. Walgreens cited two people as being primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The first was a representative from the Loss Prevention department who said her department was “not equipped” to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week. The second was Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only between 10 to 100 of the thousands of orders that were deemed suspicious under the new algorithm. Walgreens did not provide Ms. Martin access to information about the area the store was serving, the order history for comparable stores, or any other data beyond the sales and order

history for that store. If an order did not “make sense” to her based on those limited resources, she testified that she would call the store or district manager or pharmacy supervisor. She lacked authority to take “direct action” on an order.

757. Walgreens has previously cited to a series of email exchanges with Ms. Martin and her deposition testimony as exemplars of its due diligence procedures under the post-2009 SOM program. In the emails, which date from January 10-11, 2011 and are between Ms. Martin and a Walgreens Distribution Center (“DC”) employee, the DC employee notes that “several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis.” The DC employee continued, with respect to a single store, “we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don’t know how they can even house this many bottles to be honest. How do we go about checking the validity of these orders?” Ms. Martin noted that the store had average weekly sales of 36,200 dosage units, which was equal to 362 bottles per week, stating, “I have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles).” Ms. Martin then told the DC employee that she could call the district pharmacy supervisor to see if he “may be able to shed some light on the subject.” Despite the fact that questions had been raised about this store ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy, which was located in a town of less than 3,000 people.

758. In her deposition, Ms. Martin stated that she never even attempted to determine the size of the community that was receiving these “huge quantities” of oxycodone. She further testified that she was not near that store, did not have access to the store’s prescriptions or patient information, and as noted above, couldn’t take any “direct action.” Approximately 18 months

after this email exchange, as a result of DEA action, Walgreens agreed to surrender its DEA registration for this same store that Ms. Martin reviewed as part of her exemplary “due diligence.”

759. In the ISO regarding the Distribution Center, the DEA found specifically regarding the orders that were the subject of these email exchanges, that “[b]ased on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy.” The DEA further found regarding this purported “due diligence,” that Walgreens “failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels.” The DEA noted that “[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores.”

760. These failures were not limited to the specific Florida pharmacies and distribution center described above; instead, they reflect systemic failures of Walgreens’s SOM system that impacted its distribution in the County, as well. Walgreens admits that the SOM systems and procedures at all of its DCs were the same, including those at the facilities that continued shipping opioids into the Plaintiff County. Accordingly, it is not surprising that, in February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg DC in Ohio to those issued to the Jupiter DC in Florida. Walgreens employees made plans in preparation for the Perrysburg DC being “shut down” by the DEA, like the Jupiter DC. Within weeks of receiving the six subpoenas and warrant, Walgreens decided to “discontinue

distribution of controlled substances from the Perrysburg facility” in order to “eliminate any immediate need for further DEA administrative action” regarding the Perrysburg facility.

761. Further, after the DEA began its investigation, Walgreens held meetings with and informed the DEA that it was implementing “new changes” to “enhance” its SOM program. Internal documents reveal that Walgreens improved its SOM program only “in an effort to convince the DEA that the proposed penalty is excessive.”

762. Even so, by November 2012, the program still did not halt the orders for due diligence evaluation or report the orders as suspicious. Further, at that time, the program began to automatically reduce orders that violated ceiling thresholds.

763. There also is no evidence that these flagged or cut orders were reported as suspicious to the regulatory authorities.

764. As a result of the DEA investigation, Walgreens formed the Pharmaceutical Integrity (“Rx Integrity”) Team in 2012, purportedly to make sure that those types of failures did not continue. However, the group’s true role was protecting Walgreens’s Distribution Centers and stores from losing their DEA licenses. The effort was only for show. Walgreens never provided the Rx Integrity group the resources needed to achieve due diligence on the large number of orders identified by Walgreen’s SOM program for the company’s 5,000 plus stores.

765. In December 2012, the further enhanced SOM system flagged “14,000 items that the stores ordered across the chain that would have to be investigated” before they could be shipped.<sup>222</sup> Walgreens admitted that yet again it did not have sufficient resources to timely review these orders. Walgreens noted that “[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution

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<sup>222</sup> WAGMDL00659270.

centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances.” At the time, these 14,000 orders were flagged Walgreens Rx Integrity Team was comprised of fewer than five people.<sup>223</sup> Even at its height, Rx Integrity had only eleven employees. Instead of sufficiently staffing the SOM program, Walgreens recognized it had the ability to control its due diligence workload by increasing the stores’ ceiling levels, and thereby reducing the number of orders that would hit that ceiling and result in a flag.

766. As described below, Walgreens admits to failures in its suspicious order monitoring prior to 2012. Comparing the 2013 SOM system to the previous system, one of Walgreens’s Pharmaceutical Integrity Managers in August 2013 explained:

The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override The purpose for this is to ensure we have performed adequate review before sending in additional inventory.

The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens.<sup>224</sup>

767. Yet, even in 2013, orders being flagged as suspicious for review before shipment were “a week old” before they made it to the review team, often “ha[d] already been shipped,” and were not being reported.

768. Walgreens never equipped its distribution operations to monitor, report, and halt suspicious orders, or otherwise effectively prevent diversion. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to

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<sup>223</sup> Polster Dep., at 240:3-15.

<sup>224</sup> WAGMDL00021425.

cease controlled substance distribution all together. Walgreens stated that “while the financial impact of no longer [self distributing] from the Walgreens DCs was taken into consideration,

769. there is a greater risk to the company in fines and loss of licenses if we continue to sell these items in our warehouses.”

770. Indeed, with respect to Walgreens’s suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Order [Denying Walgreen’s Motion for Summary Judgment], MDL No. 2804, Doc. 2569 (N.D. Ohio Sept. 4, 2019).

771. Although Walgreens purported to have in place “Good Faith Dispensing” (“GFD”) Policies for many years, it failed to meaningful apply policies and procedures, or to train employees in its retail pharmacies on identifying and reporting potential diversion.

772. Despite knowing that prescribers could contribute to diversion, and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens’s dispensing policies, which it titled “Good Faith Dispensing”, or “GFD”, explicitly instructed pharmacists who “receive[] a questionable prescription” or otherwise were “unable to dispense a prescription in good faith” to “contact the prescriber” and, if “confirm[ed]” as “valid” by the prescriber, to then “process the prescription as normal.” Further, though Walgreens’s policies listed a handful of “questionable circumstances,” such as “increased frequency of prescriptions for the same or similar controlled drugs by one prescriber[,] for large numbers of patients [,] for quantities beyond those normally prescribed,” it is unclear what, if any, resources Walgreens made available to its pharmacists for checking these vague criteria, which, in any event, became meaningless if a prescriber “confirm[ed]” the prescription as

“valid,” by calling the prescriber. For example, in 2010 when a pharmacy manager expressed concern about significant numbers of opioid prescriptions from pain clinics, and being help responsible for “excessive c2 rx dispensing,” her district supervisor instructed her “not [to] refuse script for large quantities” but simply to “call the MD’s, document it on the hard copy[,] and that is all that is needed to protect your license.” Despite internally recognizing that “a prescriber of a controlled substance prescription [may be] involved in diversion”, Walgreens’s GFD policies continued to endorse calling the doctor as a greenlight to any “questionable” prescription.

773. In 2012, Walgreens finally removed the “process the prescription as normal” language from its formal GFD policies, admitting that under the law “it is not enough to get confirmation that the prescriber wrote the prescription.” However, Walgreens still failed to ensure it complied with its duties.

774. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present. To be clear, this required no inquiry into whether an opioid prescription was the proper treatment for a particular patient; instead, as a registrant, Walgreens was obligated, and failed, to implement policies and procedures at a corporate level to identify and address signs of diversion. *Compare United States v. Hayes*, 595 F.2d 258 (5th Cir. 1979) (“It is also evident that a pharmacist can fulfill his responsibility under s 1306.04 without practicing medicine. The facts of this case show how a pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.”).



775. Indeed, during the course of a 2009 DEA investigation into Walgreens dispensing noncompliance, Walgreens internally noted that it currently had “no training” for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the legitimacy of prescriptions coming from Florida, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens’s attitude that profit outweighed compliance with the law or protecting public health.

776. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all “Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances,” requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreen Co. was required to create a nationwide “compliance program to detect and prevent diversion of controlled substances as required by the . . . [CSA] and applicable DEA regulations.” Pursuant to the MOA, the “program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills” as well as “routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA.” Further, Walgreens was required to “implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations.”

777. Walgreens would also make more promises in a 2013 MOA with the DEA, described further below, related to failures to that lead to the ISOs described above.

778. Even after development and a relaunch of its GFD policy in response to settlements with the DEA, however, Denman Murray, Director of Rx Supply Chain Retail, stated in an MDL deposition that, “traditionally, we’ve always treated a controlled substance like any other, [a] widget’s a widget to the system.”

779. Further, after the GFD “relaunch” in April 2014, a Walgreens “RxIntegrity” presentation focused on Walgreens “Market 25,” but also assessing “average market” trends, reported that “pharmacists [were] not being too strict with GFD, nor [were] they losing volume.”

780. As with distribution, Walgreens failed to allocate appropriate resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were “challenged to get into the stores” and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a “high number of stores” and their time was consumed with “people processes, business planning, market and district meetings,” such that supervision in store was being handled informally by “community leaders” who have “limited formal authority.”

781. A Walgreens internal audit performed after the 2013 DEA settlement confirms that Walgreens’s supervision and compliance failures continued. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient “store walk program” existed to monitor target drug good faith dispensing requirements and no corporate reporting was being generated, and employees were failing to timely complete Good Faith Dispensing training, such that, at the time of the

audit, over 35,000 employees had not completed their required training for that year.

Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure. However, documents from 2016 regarding monthly store compliance walks indicate that during the monthly "Compliance Walks" to "verify compliance ... [with] regulatory requirements in... pharmacy areas," substantially no dispensing compliance supervision occurred, outside of ensuring the pharmacy was verifying the patient's address on five sample prescription fills.

782. Unsurprisingly, compliance with GFD and TD GFD has been poor. For example, in 2014 Walgreens discovered a pharmacist who failed to follow GFD for five to six months without being discovered by supervisors. In 2014, Rx Integrity noted dozens of stores dispensing opioids without performing the required checks. In certain cases, the pharmacists were unaware of the GFD procedures or had been told by supervisors to disregard them.

783. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens was "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with the DEA. In Walgreens's own words, "Results were unfavorable." Fewer than 60% of stores were complying with TD GFD with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.

784. The "Big Three" wholesalers, Cardinal, McKesson, and AmerisourceBergen, gave deferential treatment to chain pharmacies, such as Defendants. An internal Cardinal document for example, stresses that "certain chain pharmacies refuse to allow any sort of

administrative inspection by Cardinal or to make certifications” and that large, national chains can “take their billions upon billions of dollars in business to any wholesaler in the country.”

785. Thus, for example, in 2008, Cardinal prepared talking points for a NACDS Conference about its planned retail chain SOM program, making it clear that the program would “minimize the disruption” to retail chains and that they would “work together” with the pharmacies “to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt” business. Cardinal also provided warnings to chain pharmacies, including Walgreens, that they were approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase. Such “early warnings” were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by “flagging the stores at 75%,” it could “avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA.”

786. Preferential treatment of Walgreens ultimately was not enough for Cardinal to keep Walgreens’s business, however. In 2013, Walgreens entered a ten-year agreement with AmerisourceBergen Drug Company. The shift to AmerisourceBergen as its exclusive supplier prompted Cardinal to complain: “we bailed you guys out when you had your [DEA] issues.”

787. By 2017, Walgreens accounted for 30% of AmerisourceBergen’s revenue.

788. AmerisourceBergen was similarly deferential, allowing Walgreens to “police their own orders and block any order to [AmerisourceBergen (“ABC”)] that would exceed ABC’s threshold thus triggering a suspicious order being sent to DEA from ABC. Additionally, when AmerisourceBergen received orders from Walgreens “outside the expected usage,” Walgreens and AmerisourceBergen met to discuss adjusting thresholds or using “soft blocking.” Contrary to

DEA guidance and its own stated policy, AmerisourceBergen also shared the threshold limits set by its “order monitoring program” with Walgreens, and also provided Walgreens with weekly SOM statistics. AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.<sup>225</sup>

789. Walgreens also owns 26% of AmerisourceBergen’s stock. In 2018, after a coalition of AmerisourceBergen shareholders sought greater transparency from its Board related to the “financial and reputational risks associated with the opioid crisis,” Walgreens, together with other insiders, reportedly leveraged this position to defeat the proposal, which enjoyed majority support among the independent shareholders.

790. As described above and further below, as both a distributor and a dispenser, upon information and belief, Walgreens ignored red flags of diversion in Plaintiff’s Communities.

791. Walgreens violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

792. The volume of opioids Walgreens shipped into, and dispensed from locations in, the County was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

793. Yet, upon information and belief, Walgreens did not timely report any suspicious order in Plaintiff’s Communities between 2007 and 2014. Instead, Walgreens funneled far more opioids than could have been expected to serve legitimate medical use and ignored other red

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<sup>225</sup> Rite Aid received similar accommodations from McKesson, which forwarded it dialed monitoring reports so that Rite Aid could “let [McKesson know] if it needed to make any adjustments to its thresholds. MCKMDL00646634.

flags of suspicious orders. This information, along with the information known only to distributors such as Walgreens (especially with its pharmacy dispensing data), would have alerted Walgreens to potential diversion of opioids.

794. In addition, Walgreens also distributed and dispensed substantial quantities of prescription opioids in other states, including Florida, as described above, and these drugs were diverted from these other states into this state. Walgreens failed to take meaningful action to stop this diversion despite its knowledge of it, and it contributed substantially to the opioid epidemic in Plaintiff's Communities.

795. Walgreens knew the flood of pills being supplied into Florida were being diverted. Walgreens also knew that the DEA was conducting a "crackdown on Florida pharmacies where the market is notorious for illicit prescription painkillers" and that Walgreens's own pharmacies accounted for 53 of the top 100 retail sellers of oxycodone in Florida. Walgreens knew as well that these pills being sold into the "epicenter[s] of [the] notorious well-documented epidemic of prescription drug abuse... were migrating to other states," and that many "prescriptions [were] not for a legitimate medical purpose."

796. Walgreens also developed and maintained highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time and depicted the exact amounts of pills, pill type, and anticipated order threshold for its own stores.

797. Through this proprietary data, Walgreens had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids. It used this data to evaluate its own sales activities and workforce. Walgreens also was in possession of extensive data regarding individual doctors' prescribing and dispensing to its customers, the percentage of

a prescriber's prescriptions that were controlled substances, individual prescription activity across all Walgreens stores, and the percentages of prescriptions purchased in cash. Such data are a valuable resource that Walgreens could have used to help stop diversion, but it did not.

798. Upon information and belief, Walgreens, by virtue of its data analytics, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walgreens ignored these obvious red flags.

799. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

800. Upon information and belief, Walgreens failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

801. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to conduct reviews to adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create

policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

802. Discovery will reveal that Walgreens knew or should have known that its pharmacies were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription “cocktails”; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walgreens had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

803. Walgreens admits its role in the opioid epidemic, stating it has the “ability – and [] critical responsibility – to fight the opioid crisis” as the “nation’s largest pharmacy chain” in a time when “[a]ddiction to prescription painkillers, heroin, and other opioids has surged, with opioid overdoses quadrupling in this decade” and “drug overdose deaths – the majority from prescription and illicit opioids” resulting in “more fatalities than from motor vehicle crashes and



gun homicides combined.” Walgreens also admits the “opioid crisis” is caused by “misuse, abuse and addiction” that result from the “flow of opioids that fuel the epidemic.”

### **iii. Rite Aid**

804. Rite Aid distributed Schedule III (“CIIIs”) controlled substances (e.g., hydrocodone combination products) to its own Rite Aid stores until late 2014. Rite Aid distributed through its Perryman Distribution Center (Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center) and its Liverpool Distribution Center (Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center), both DEA registrants.

805. Rite Aid’s controlled substance distribution process was fairly simple. Rite Aid used a computerized “auto-replenishment system” (ARS) through which individual Rite Aid pharmacies would generate orders that were sent to the distribution center (DC). This ARS relied directly on dispensing data and the dispensing patterns of individual Rite Aid stores. If the ARS generated an order that was above Rite Aid’s universal 5,000 dosage-unit (DU) threshold, the DC employees filling the order were supposed to manually recognize that the order was above threshold. If they did observe an order over threshold, the only “review” of the order was an attempt to call the pharmacy that placed the order to verify the order amount was correct (i.e., that it was not a “fat-finger” error). If the pharmacy confirmed that the above-threshold order amount was correct, or if the DC simply could not contact the pharmacy, the order was cut to the threshold and shipped. All the above-threshold orders were supposed to be maintained on a handwritten log containing only basic information about the order.

806. After the orders had shipped, Rite Aid monitored its inventory through its Navicase/Naviscript system. The Rite Aid Asset Protection Department used “key performance indicators” (KPIs) to analyze data about ordering from the Rite Aid stores to identify diversion through theft. Yet, as numerous Rite Aid witnesses have testified, Rite Aid did not use the

Navicase/Naviscript system to identify—much less report—suspicious orders. Furthermore, assuming that the Navicase/Naviscript could identify suspicious orders, the Navicase/Naviscript data analysis only took place after shipment. Moreover, Rite Aid’s 30(b)(6) representative in the MDL, Janet Getzey Hart, testified that the “asset protection KPIs were utilized to review orders and then lead to diversion cases if there were some issues with it,” but “they were not used to report suspicious orders.”

807. Rite Aid maintained a small, inadequate list of suspicious prescribers but did not make any efforts to identify or report any suspicious orders from stores Rite Aid knew were dispensing prescriptions for those suspicious prescribers. Further, given that orders would have already shipped, Rite Aid did not incorporate “suspicious prescriber” information that it may have collected in determining whether an order from any location was suspicious.

808. Ultimately, Rite Aid’s distribution system made it nearly impossible for any order to be identified, much less reported, as suspicious. As a result of the company’s policies and procedures, Rite Aid did not – and indeed, could not – identify what was unusual because all Rite Aid DCs had a static, blanket threshold for all Rite Aid stores above which Rite Aid would cut the order. The threshold, which never changed, was set at of 5,000 DUs, per national drug code (NDC), per order (although Rite Aid does not know why it was set at 5,000 DUs). Rite Aid stores typically ordered once per week, but some stores ordered twice per week and others ordered every two weeks. That means that at its lowest, the Rite Aid threshold was 10,000 DUs per month, per store and at its highest it was 40,000 DUs per month, per store.

809. Despite the extremely high threshold amount, Rite Aid did not have a procedure that required anyone to report an order that came in over the universal threshold as suspicious. Instead, DC employees would “cut” the order down to the threshold and then ship the order. Rite

Aid did no due diligence on orders that came in over the blanket threshold. An overwhelming number of the “cut” orders, if not all, were not reported to the DEA until after the fact, if at all.

810. Rite Aid also had little to no records about past order history to determine if an order was suspicious. The Perryman DC kept what was called a “Threshold Log,” which contained in hard copy only basic information about orders that exceed the threshold: date of order, store number, item number, item description, quantity ordered, allowable quantity, and the reason for the allowable quantity. But, any use of the log to potentially identify suspicious orders was only done sporadically and after the above-threshold orders were cut and shipped.

811. Additionally, Rite Aid placed the responsibility to identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency on employees whom the DEA coordinator at the Rite Aid’s distribution center, testified were not able to actually do so.

812. Recognizing its failure to have a system, Rite Aid did begin to develop a suspicious order monitoring system for the first time in 2013. In documenting such efforts, Rite Aid stated as follows:

The purpose of this project is to develop effective controls against the diversion of controlled substances and conduct adequate due diligence to ensure that controlled substances distributed from the Distribution Centers are for legitimate patient needs. Rite Aid must ensure compliance with 21 U.S.C. 823 and/or C.F.R. 1307.74(b) to detect and report suspicious orders of controlled substances through the Distribution Centers.

813. In the end, however, Rite Aid never adopted the new SOM system because it stopped distributing controlled substances before this system could be implemented.

814. With respect to Rite Aid’s suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence

regarding the inadequacy of its SOM system in that litigation. *See* Opinion and Order [Denying Rite Aid’s Motion for Summary Judgment], MDL No. 2804, Doc. 3100, 2020 WL 425940 (N.D. Ohio Jan. 27, 2020).

815. Rite Aid conspired with McKesson to avoid suspicious order reporting. McKesson was Rite Aid’s exclusive wholesaler for Schedule II controlled substances, including opioids, during the relevant time period. Rite Aid also ordered CIIIs from McKesson during the relevant time period. Rite Aid ordered CIIIs from McKesson not only when it stopped self-distributing in late 2014, but McKesson also supplemented Rite Aid stores’ supply of Schedule III controlled substances during the period when Rite Aid self-distributed controlled substances.

816. McKesson provided Rite Aid with notification of stores hitting McKesson’s thresholds and regularly granted threshold increases without conducting any due diligence. For example, when a McKesson report revealed a number of Rite Aid stores were at 90% of their threshold and about to be flagged, McKesson offered to – and did – increase the thresholds for all Rite Aid locations by 50%. McKesson also forwarded daily monitoring reports to Rite Aid so that Rite Aid could “let [McKesson] know” if McKesson “need[ed] to make any adjustments to current thresholds.”

817. On one occasion, Rite Aid noted that over 10% of its stores came close to being blocked, and McKesson simply asked Rite Aid how high it wanted the thresholds increased. McKesson also prompted Rite Aid to delay its orders until the next month in order to avoid hitting monthly thresholds when they were getting close.

818. Rite Aid allowed its stores to order from McKesson without any restriction and failed to take those orders into account in Rite Aid’s self-distribution SOM system, negating any constraints from Rite Aid’s even limited internal controls.

819. Rite Aid violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

820. Upon information and belief, Rite Aid funneled far more opioids into Plaintiff's Communities than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Rite Aid (especially with its pharmacy dispensing data), would have alerted Rite Aid to potential diversion of opioids. Yet, Rite Aid admits that it never identified any suspicious orders before or after shipment, much less reported any suspicious orders to the DEA.

821. Upon information and belief, Rite Aid, by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Rite Aid ignored these obvious red flags.

822. Rite Aid therefore, was aware of the suspicious orders that flowed from its distribution facilities. Rite Aid refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Rite Aid failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids.

823. Upon information and belief, Rite Aid failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community;

(b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

824. Rite Aid was, or should have been, fully aware that the opioids it distributed and dispensed were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to identify and report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

825. Given Rite Aid retail pharmacy operations, in addition to its role as a wholesale distributor, Rite Aid knew or reasonably should have known about the disproportionate flow of opioids and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

826. Rite Aid pharmacies routinely have dispensed opioids in violation of the CSA and accompanying regulations. Such conduct was a result of Rite Aid’s lack of robust policies and procedures regarding dispensing controlled substances as well as Rite Aid’s focus on profitability over its legal obligations and public safety.

827. Rite Aid’s dispensing policies and procedures used at all its Rite Aid pharmacies nationally were deficient in many ways.

828. Rite Aid implemented a policy for dispensing “high-alert” controlled substances for the first time in 2013. The policy was a simple checklist consisting of six steps: 1) Receive the prescription; 2) Validate the Prescription; 3) Validate the Prescriber; 4) Validate the Patient; 5) Decide to dispense or not to dispense; and 6) Report any suspicious activity. Yet Rite Aid provided little to no guidance on how to perform the vague tasks and the policy was little more

than words on a page. In another example, Rite Aid only started to alert its pharmacists of patients' attempts to get early refills – a red flag of diversion – in 2016.

829. Rite Aid also did nothing to ensure that even its pro forma policies were being followed. Rite Aid did not audit its pharmacies for compliance with its own controlled substances dispensing policies or compliance with the CSA's requirements regarding legal dispensing.

830. As a sophisticated, national chain pharmacy, Rite Aid had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Its own data would have allowed Rite Aid to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper or illegitimate prescribing.<sup>226</sup>

831. Yet, Rite Aid only started tracking "High Alert data" in September, 2015 at the corporate level. Even then, it did not use the data to effectively comply with its legal obligations to prevent diversion and ensure only legal prescriptions were being filled at its pharmacies. For example, Rite Aid provided its pharmacists no visibility into the data it collected, thereby depriving them of an invaluable resource when evaluating prescriptions.

832. In contrast to its lack of robust policies to ensure only prescriptions issued for a legitimate medical purpose were dispensed, Rite Aid had numerous and detailed policies regarding metrics to ensure its profitability. These policies ensured that Rite Aid pharmacists did not have the time, resources, or support to adequately discharge not only their legal duties as pharmacists, but also their alleged duties under Rite Aid's own policies and procedures.

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<sup>226</sup> See, e.g., *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315 (Dep't of Justice Oct. 12, 2012) (decision and order) (DEA expert witness examined dispensing records alone to identify inappropriately dispensed medications).

833. For example, in 2011, Rite Aid adopted a policy whereby it promised to fill prescriptions in 15 minutes or less.<sup>227</sup> If a prescription took more than 15 minutes to fill, the patient would get a \$5 gift card. Rite Aid touted the program as something consumers wanted, but many others recognized the danger such a program was to patients and the practice of pharmacy. Numerous State Boards of Pharmacy objected to the program. As the chair of the Illinois State Board of Pharmacy said: “This is 180 degrees away from everything we are trying to do in moving the pharmacy profession toward being patient information-focused rather than product-focused. And it's counter to our many efforts to improve patient safety.”

834. Despite eventually doing away with the 15 minute or less promise, Rite Aid continued to carefully track its pharmacists’ prescription fill speeds, thereby ensuring that the pharmacists were not able to exercise their corresponding responsibility under the law. In fact, Rite Aid pharmacies routinely filled prescriptions at a pace of multiple prescriptions per minute.

835. Rite Aid’s compensation policies also blocked pharmacists from preventing illegitimate prescriptions from being dispensed. Rite Aid’s compensation policies provided bonuses that depended on the number of prescriptions—including opioids—dispensed from Rite Aid pharmacies. Even when Rite Aid eventually, ostensibly removed controlled substances from its bonus calculations, Rite Aid continued to evaluate its pharmacies on their profitability. Indeed, pharmacists’ jobs depended on the profitability of the pharmacy; if the pharmacy was not profitable enough staff would be laid off or it would be closed entirely. A pharmacy’s profitability is heavily dependent on its prescription volume, including controlled substances. So even if removed from bonus calculations, the amount of prescriptions dispensed by a pharmacy

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<sup>227</sup> Drug Topics, Rite Aid offers 15-minute Rx guarantee, May 15, 2011, <https://www.drugtopics.com/chains-business/rite-aid-offers-15-minute-rx-guarantee>.



and corresponding effect on a pharmacy's bottom line still acted as a powerful incentive for pharmacies to focus on dispensing all prescriptions, instead of only legal ones. Rite Aid did nothing to counter this perverse incentive and, in fact, encouraged profit over patients.

836. The problem of illegal dispensing caused by Rite Aid's focus on quickly filling prescriptions and increasing the number of prescriptions dispensed was also exacerbated by Rite Aid's inadequate pharmacy staffing. Often, single pharmacists were left as the only pharmacist at a location for entire shifts. This greatly cut into the ability of the pharmacist to evaluate each prescription carefully and in accordance with the law.<sup>228</sup>

837. Rite Aid also evaluated its pharmacies on customer service. Perversely though, Rite Aid considered its pharmacist's refusal to fill a prescription as a "service failure," despite their pharmacist's legal obligation to refuse to fill certain prescriptions.

838. The effect of Rite Aid's actions was all too predictable and tragic.

839. As a vertically integrated distributor and dispenser of prescription opioids, Rite Aid knew or should have known that an excessive volume of pills was being sold or diverted into Plaintiff's Communities.

840. The sheer volume of prescription opioids distributed to and dispensed by Rite Aid pharmacies is indicative of potential diversion and required appropriate due diligence.

841. Discovery will reveal that Rite Aid knew or should have known that its pharmacies were (a) filling multiple prescriptions to the same patient using the same doctor; (b)

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<sup>228</sup> Some states have tried to outlaw pharmacists from working alone. California, for example, passed a law saying no pharmacist could be required to work alone. Regrettably, however, it has been largely ignored since taking effect last year, according to leaders of a pharmacists' union. See Gabler, Ellen, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, THE NEW YORK TIMES (Jan. 31, 2020), <https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html>

filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription “cocktails”; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Rite Aid had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

842. Because of its vertically integrated structure, Rite Aid has access to complete information regarding red flags of diversion across its pharmacies, but Rite Aid failed to utilize this information to effectively prevent diversion.

#### **iv. Walmart**

843. Walmart is the largest private employer in the United States by far. It employs more than 1.5 million people. But for years, Walmart chose not to assign a single employee to design or operate a system to detect suspicious orders of controlled substances. Walmart chose to do nothing while hundreds of thousands of people were dying and waited until 2014 to begin to take meaningful action. By that time, it was too late.

844. Like other Defendants, Walmart self-distributed opioids to its retail stores.

845. Specifically, Walmart operated registered distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018 when it ceased self-distributing controlled substances. Walmart’s conduct is particularly troubling given that it acted both as a self-distributing and dispensing pharmacy for such a long period of time.

846. Prior to 2011, Walmart had not designed any formal system to identify suspicious orders of controlled substances and, therefore, utterly failed to meet its statutory obligations.

847. Walmart has claimed that its hourly employees and associates—who were also responsible for filling orders at Walmart Distribution Centers—monitored the orders they were filling for unusual size, pattern, and frequency. Typically, this “review” involved between 700 and 800 orders a day. Walmart has also claimed that these hourly associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.

848. Upon information and belief, Walmart can produce no written evidence of any such instructions to Walmart associates, no evidence of any training that would be required to implement such a procedure, or anyone being alerted about an unusual order or performing any follow up inquiry.

849. Walmart failed to provide any guidance to the associates as to what constitutes a “suspicious” order. Instead, Walmart emphasized its associates’ subjective judgment based on their “knowledge and experience” as distribution center employees. There is no evidence that any Walmart employee ever flagged an order as suspicious prior to 2011.

850. Walmart purportedly implemented a “monitoring program” that would identify suspicious orders of controlled substances in 2011. This system purportedly was in place until 2015.

851. Walmart's monitoring program was insufficient to identify suspicious orders of controlled substances. The program flagged only very large orders of controlled substances. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders of more than 20 bottles (2,000 dosage units) that were 30% higher than a rolling four-week average for that item. Orders under 2,000 units per week were never flagged, meaning that a pharmacy could order 8,000 units per month without ever being flagged. Moreover, that meant that even if an order was more than 30% greater than the four-week average, it could not draw an alert unless it also was more than 20 bottles.

852. Under this system, an alert did not mean Walmart would report the order or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart never reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart simply cut the order to the amount of the 50 bottles threshold and shipped it. Walmart never reported cut orders to the DEA. Although information regarding flagged orders was available and sent daily to Walmart's headquarters in Arkansas (the "Home Office"), no one from the Home Office ever reviewed or took any action regarding flagged orders.

853. This practice continued until mid-2012 when Walmart implemented "hard limits" on opioid orders. Under this approach, weekly orders of Oxycodone 30mg ("Oxy 30") were automatically reduced to 20 bottles. Still, Walmart failed to report the orders to the DEA.

854. During this time period, Walmart also monitored weekly orders of other controlled substances in quantities of more than 20 bottles. Specifically, an "Over 20 Report" was provided to the Home Office in the morning and if nothing was done by mid-afternoon, the

orders were filled and shipped. Upon information and belief, there is no evidence of any order in fact being held or reviewed pursuant to this practice.

855. Further, cutting the order did not mean that the Walmart pharmacy would not receive the full supply. Walmart pharmacies also purchased opioids from outside suppliers, including McKesson and AmerisourceBergen. Pharmacies could place another order with these outside vendors to make up the difference, or in some cases, have orders fulfilled by both Walmart and a third-party distributor at the same time. Thus, even though Walmart had the ability to monitor such orders, it chose not to, which allowed its pharmacies to surpass its already high thresholds by simply ordering drugs from a third party.

856. Walmart knew that its monitoring program was insufficient to fulfill its obligations to prevent diversion. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. It also stated that it was “TBD” when Walmart would develop such a system. In June 2014, Walmart again acknowledged that it lacked a compliant monitoring program. Moreover, Walmart acknowledged in 2014 that it had “no process in place” to comply with government regulations and that this created the “severe” risk of “financial or reputational impact to the company.”

857. It was not until late 2014 that Walmart’s written policies and procedures required orders of interest to be held and investigated.

858. In 2015, Walmart enhanced its suspicious order monitoring policy by implementing store-specific thresholds. Upon information and belief, it based these thresholds on the standard deviation of a specific pharmacy’s order history for each controlled substance. The

thresholds also included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency.

859. Walmart’s corporate designee, testifying on its behalf in the MDL, conceded that thresholds were set for business purposes, not for the purpose of “main[taining] of effective controls against diversion . . . into other than legitimate . . . channels ” 21 U.S.C.A. § 823(a)(1), (b)(1). Further, for almost all Walmart pharmacies, this minimum was set at 2,000 dosage units per week (or 8,000 dosage units per month). Accordingly, even when Walmart implemented a store specific policy that took into consideration a pharmacy’s order history, the program was still woefully deficient because it did not account for changes in ordering patterns. A pharmacy could, for example, go from ordering 10 dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged or reviewed.

860. With respect to Walmart’s suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of Walmart’s suspicious order monitoring efforts in that litigation. *See* Opinion and Order Denying Walmart’s Motion for Summary Judgment, MDL No. 2804, Doc. 3102 (N.D. Ohio Jan. 27, 2020). In doing so, it “noted[d] the record evidence suggests obvious deficiencies that a layperson could plainly recognize.” *Id.* at 4 n. 12.

861. Upon information and belief, the volume of opioids Walmart shipped, sold, or diverted into Plaintiff’s Communities was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

862. Yet, upon information and belief, Walmart did not report a single suspicious order between 2007 and 2014. Instead, Walmart funneled far more opioids than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This

information, along with the information known only to distributors such as Walmart (especially with its pharmacy dispensing data), would have alerted Walmart to potential diversion of opioids.

863. In addition, Walmart, upon information and belief, also distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to this state. Walmart failed to take meaningful action to stop this diversion despite its knowledge of it, and it contributed substantially to the opioid epidemic in Plaintiff's Communities.

864. Walmart violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

865. For years, per capita opioid prescriptions in this state exceeded the national average and increased in ways that should have alerted Walmart to potential diversion. Indeed, as a vertically integrated, national retail pharmacy chain, Walmart had the ability to detect diversion in ways third-party wholesale distributors could not by examining the dispensing data from their own retail pharmacy locations.

866. Given the volume and pattern of opioids distributed, Walmart was, or should have been aware that opioids were being oversupplied into the state and should have detected, reported, and rejected suspicious orders. Yet, the information available shows it did not.

867. Upon information and belief, Walmart by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as

oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walmart ignored these obvious red flags.

868. Walmart therefore, was aware of the suspicious orders that flowed from its distribution facilities. Walmart refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Walmart failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids.

869. Upon information and belief, Walmart failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

870. Walmart was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

871. Given Walmart's retail pharmacy operations, in addition to its role as a wholesale distributor, Walmart knew or reasonably should have known about the disproportionate flow of opioids and the operation of "pill mills" generating opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

872. Walmart, throughout the relevant time period, owned and operated pharmacies throughout the United States, including pharmacies in Plaintiff's Communities. Through its



wholly owned or controlled subsidiary companies, Walmart operates over 4,500 retail pharmacies across the U.S., a mail-order pharmacy, a specialty pharmacy, and six pharmacy distribution centers that distribute to other Walmart entities.

873. Walmart set policies for its pharmacies at the corporate level. Walmart also presented, through nationwide advertising, a public image of the safety and excellence of all the pharmacists the company hired. In a recruitment video for pharmacists on Walmart's YouTube channel, the company shows Walmart pharmacists speaking about working at the company: "the safety and the excellence we carry to our patients is phenomenal," adding that "the culture that our company has [is] respect for the individual, service, and excellence, and, of course, we always have integrity."<sup>229</sup> The commercial also states that Walmart's pharmacists "strive for excellence" and are "passionate about providing quality healthcare."

874. Walmart pharmacies received distributions of prescriptions from Walmart's distribution centers and from other wholesale distributors, which enabled these pharmacies to have the same orders filled by both Walmart and a third-party distributor.

875. The volume of prescription opioids dispensed by Walmart pharmacies in and around Plaintiff's Communities is indicative of potential diversion and required appropriate due diligence.

876. As a vertically integrated distributor and dispenser of prescription opioids, Walmart had unique insight into all distribution and dispensing level data and knew or should have known that it was dispensing an excessive volume of pills.

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<sup>229</sup> Walmart, *Your Career as a Walmart Pharmacist* (Sept. 25, 2014), available at <https://www.youtube.com/watch?v=9VD12JXOzfs> (last visited May 13, 2020).

877. Discovery will reveal that Walmart knew or should have known that its pharmacies were: (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines or prescription “cocktails”; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walmart had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

878. Walmart had complete access to all prescription opioid distribution data related to Walmart pharmacies.

879. Walmart had complete access to all prescription opioid dispensing data related to Walmart pharmacies.

880. Walmart had complete access to information revealing the doctors who prescribed the opioids dispensed in Walmart pharmacies.

881. Walmart had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in Walmart pharmacies.

882. Walmart had complete access to information revealing the opioids prescriptions dispensed by Walmart pharmacies.

883. Walmart had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by Walmart pharmacies.

884. Walmart had complete access to information revealing the size and frequency of prescriptions written by specific doctors across Walmart pharmacies.

885. Yet, Walmart failed to put in place effective policies and procedures for the dispensing of prescription opioids and failed to provide adequate guidance to its pharmacists on dispensing opioids. Moreover, Walmart's pressure on pharmacists to fill more prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number of prescriptions a pharmacy filled and profit that the pharmacy generated. Upon information and belief, controlled substances were included in Walmart's pharmacy incentive program for most of the relevant time period. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, because of Walmart's drive for speed, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence.

886. Even when Walmart pharmacists suspected diversion based on an individual prescriber's prescribing practices, for years, Walmart did not allow its pharmacists to request blanket refusals to fill. Walmart, however, had always had the ability to do so. Finally, in 2017, Walmart implemented a policy by which individual pharmacists could request such blanket refusals, which would permit the pharmacist to refuse to fill future prescriptions from that prescriber without evaluating each prescription individually. In addition, Walmart also always

had the ability to “centrally block” problematic prescribers across all Walmart and Sam’s Club pharmacies but did not establish a procedure to do so until 2017. In the “Practice Compliance” document describing this policy, Walmart admitted that it may, “in certain situations,” have information about prescribing practices that is not available to individual pharmacists:

While pharmacists are in the best position to determine whether individual prescriptions are appropriate, additional information may be obtained that is not available to our pharmacists. Therefore, in certain situations, a prescriber may be identified whose prescribing practices raise concerns about prescribing controlled substances for legitimate medical purposes. After a thorough review, these additional insights may lead Walmart to place a block in Connexus on controlled substance prescriptions from these prescribers.

887. Moreover, Walmart’s policies and procedures often were at odds with the pressure for pharmacists to fill prescriptions quickly. Pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence.

888. These systemic issues are reflected in numerous enforcement actions and investigations that demonstrate the Walmart put profits and sales ahead of compliance, its customers and communities, and public safety. In 2009, for example, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

(1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy]

knew or should have known were diverting the controlled substances.

889. In addition, a 2011 Memorandum of Agreement (“2011 MOA”) arising out of the investigation states that the DEA also learned that the same pharmacy was allegedly dispensing controlled substances based on prescriptions that lacked valid DEA numbers and allegedly refilling controlled-substances prescriptions too early.

890. Upon information and belief, the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA, which required Walmart to maintain a “compliance program” states that it is applicable to “all current and future Walmart Pharmacy locations.”

891. Following the 2011 MOA, Walmart was supposed to revamp its dispensing compliance program, but still, its policies and procedures remained deficient.

892. Instead, systemic failures continued, and Walmart’s national corporate office not only failed to insist that Walmart implement adequate controls against diversion, but they also ignored concerns raised by Walmart pharmacists.

893. One internal document from 2015, for example, notes concerns from a Walmart pharmacist that “his leadership would not support his refusing to fill any ‘legitimate’ (written by a Dr) prescriptions and he stated that his current volume/staffing structure doesn’t allow time for individual evaluation of prescriptions[.]” When this pharmacist refused to fill a customer’s controlled substance prescription because the customer was attempting to fill it too soon, the Market Health & Wellness Director for that store complained to management that the pharmacist “sent a customer to a competitor” and “expressed significant concern about how ‘sending customers away’ would impact the sales figures for the store,” and insisted that “the store needs to fill every available prescription.”

894. In October 2018, the U.S. Department of Justice (“DOJ”) had evidence that Walmart pharmacies in Texas dispensed opioids that killed customers who overdosed on the drugs. “The pharmacists who dispensed those opioids had told the company they didn’t want to fill the prescriptions because they were coming from doctors who were running pill mills,” but their pleas “for help and guidance from Walmart’s corporate office” fell on deaf ears.<sup>230</sup> Pharmacists in a number of other states also sought help from Walmart’s corporate office, also to no avail. Walmart compliance officials failed to take action in response to these alarms. “Instead, they repeatedly admonished pharmacists that they could not cut off any doctor entirely.”<sup>231</sup> Even if pharmacists believed the doctor was operating a pill mill, rather than providing genuine medical care, “[t]hey could only evaluate each prescription on an individual basis.”<sup>232</sup> In fact, a 2011 document from Walmart Regulatory Affairs regarding the “Proper Prescriber-Patient Relationship” stated, “Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber- patient relationship or a valid medical reason before refusing to fill.”

895. A Texas federal prosecutor, in connection with an investigation that began in 2016, described a systemic problem. The investigation showed Walmart’s issue was not a few rogue employees. Rather, “Walmart had a national problem.”<sup>233</sup> The investigation reportedly revealed that between 2011 and 2017, “Walmart pharmacists repeatedly filled prescriptions that

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<sup>230</sup> Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), <https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment>

<sup>231</sup> *Id.*

<sup>232</sup> *Id.*

<sup>233</sup> *Id.*

they worried were not for legitimate medical purposes, including large doses of opioids and mixtures of drugs the DEA considered red flags for abuse.<sup>234</sup> They did so even though Walmart pharmacists in Texas, Maine, North Carolina, Massachusetts, Kansas and Washington all “raised alarms to the company’s national compliance department about doctors.”<sup>235</sup> Regarding one Texas doctor who was later convicted of illegal distribution of opioids, a Walmart pharmacist wrote; “We are all concerned about our jobs and about filling for a pill mill doctor. . . Please help us.”<sup>236</sup> Another described the same doctor as a “problem,” a “liability for us,” and a “risk that keeps [him] up at night,” cautioning “[t]his is a serious situation.”<sup>237</sup> Similarly, in September 2016, a Walmart pharmacist in Pennsylvania advised that a doctor was “under investigation by the DEA for what we believe is a pill mill operation,” and that Rite Aid had begun refusing to fill his prescriptions, prompting prescriptions from this prescriber, which were “almost solely narcotic and controlled prescriptions” to double.<sup>238</sup> Still, Walmart adhered to its policy of requiring a case-by-case analysis of each prescription from the suspected pill mill placed with any Walmart pharmacy; it would not block the prescriber in its system or allow a “blanket” refusal to fill. Walmart was more concerned with the potential sale than it was with preventing diversion.

896. Upon information and belief, Walmart also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it

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<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> *Id.*

to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

897. Upon information and belief, Walmart also failed to conduct adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

**e. Multiple Enforcement Actions against the Chain Pharmacies Confirms their Compliance Failures.**

898. The Chain Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Chain Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Chain Pharmacies. The unlawful conduct by these Defendants is a substantial cause for the volume of prescription opioids and the public nuisance plaguing the County.

**i. CVS**

899. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

900. CVS is a repeat offender and recidivist: the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the United States Department of Justice (“DOJ”). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher



than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

901. Confirming its systemic failures to implement and adhere to adequate controls against diversion, CVS has repeatedly faced enforcement actions. Recently, CVS's Omnicare subsidiary agreed to pay a \$15.3 million civil penalty as part of a settlement with the DEA resolving allegations that it improperly dispensed opioids and other controlled substances to long-term care facilities without a valid prescription.

902. As recently as March 2019, CVS Pharmacy, Inc. (including all of its relevant subsidiaries and affiliates) entered into a \$535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island, acting on behalf of the United States and the DEA's Providence Office. In connection with the settlement, a DEA agent stated: "Pharmacies put patients at risk when they dispense Schedule II narcotics, which have the highest potential for abuse, without a valid and legal prescription."<sup>239</sup>

903. In August of 2018, CVS paid \$1 million to resolve allegations that CVS pharmacies throughout the Northern District of Alabama violated record-keeping requirements under the CSA and its implementing regulations, the largest civil fine paid in Alabama by a DEA registrant.

904. In June of 2018, CVS paid \$1.5 million to resolve allegations that CVS pharmacies in Long Island, New York failed to timely report the loss or theft of controlled substances, including hydrocodone, recognized as one of the most commonly diverted controlled substances.

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<sup>239</sup> <https://www.dea.gov/press-releases/2019/04/16/cvs-pay-535000-filing-invalid-prescriptions>

905. In July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.<sup>240</sup>

906. This fine was preceded by numerous others throughout the country.

907. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.<sup>241</sup>

908. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.<sup>242</sup>

909. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.<sup>243</sup>

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<sup>240</sup> Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays \$5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act>.

<sup>241</sup> Press Release, U.S. Attorney's Office Dist. of Md., *United States Reaches \$8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dep't of Just. (Feb. 12, 2016), <https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled>.

<sup>242</sup> Press Release, U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays \$600,000 to Settle Controlled Substances Act Allegations*, U.S. Dep't of Just. (Oct. 20, 2016), <https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act-allegations>.

<sup>243</sup> Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), <https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in-agreement-with-state>.

910. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.<sup>244</sup>

911. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney’s Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.<sup>245</sup>

912. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, “based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need.”<sup>246</sup>

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<sup>244</sup> Press Release, U.S. Attorney’s Office Dist. of Mass., *CVS to Pay \$3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dep’t of Just. (June 30, 2016), <https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions>.

<sup>245</sup> Press Release, U.S. Attorney’s Office Dist. of R.I., *Drug Diversion Claims Against CVS Health Corp. Resolved With \$450,000 Civil Settlement*, U.S. Dep’t of Just. (Aug. 10, 2015), <https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement>.

<sup>246</sup> Press Release, U.S. Attorney’s Office M. Dist. of Fla., *United States Reaches \$22 Million Settlement Agreement With CVS For Unlawful Distribution of Controlled Substances*, U.S.

*footnote continued on next page*

913. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.<sup>247</sup>

914. In 2013, CVS agree to pay \$11 million to resolve allegations it violated the CSA and related federal regulations at its retail stores in Oklahoma and elsewhere by: (1) creating and using “dummy” DEA registration numbers on dispensing records, including records provided to state prescription drug monitoring programs; (2) filling prescriptions from prescribers who lacked current or valid DEA numbers; and (3) substituting the DEA number of non-prescribing practitioners for the DEA numbers of prescribers on prescription records.

915. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.<sup>248</sup>

916. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.<sup>249</sup>

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Dep’t of Just. (May 13, 2015), <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution>.

<sup>247</sup> Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), <http://www.expressnews.com/business/local/article/H-E-BCVS-fined-over-prescriptions-5736554.php>.

<sup>248</sup> Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NewsOK (May 3, 2015), <http://newsok.com/article/5415840>.

<sup>249</sup> Press Release, U.S. Attorney’s Office W. Dist. of Okla., CVS to Pay \$11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dep’t of Just. (Apr. 3, 2013), <https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled>.

**ii. Walgreens**

917. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

918. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.<sup>250</sup>

919. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

920. As part of the 2013 MOA described above, Walgreens “acknowledge[d] that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA . . . and its implementing regulations.”<sup>251</sup> The 2013 MOA required Walgreens to, among other things, “maintain a compliance program in an effort to detect and prevent diversion of controlled substances” as required by law.<sup>252</sup>

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<sup>250</sup> Press Release, U.S. Attorney’s Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep’t of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

<sup>251</sup> WAGMDL00490963 at WAGMDL00490964.

<sup>252</sup> Id. at WAGMDL00490968.

921. Walgreens’ Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens’ Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.<sup>253</sup>

922. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens’ attitude that profit outweighed compliance with the CSA or the health of communities.<sup>254</sup>

923. Defendant Walgreens’ settlement with the DEA stemmed from the DEA’s investigation into Walgreens’ distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens’ corporate headquarters pushed to increase the number of oxycodone sales to Walgreens’ Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold

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<sup>253</sup> Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf’t Admin. Sept. 13, 2012).

<sup>254</sup> *Id.*

almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.<sup>255</sup>

924. An August 2013 email shows Walgreens understood the consequences of its actions, explaining that Walgreens’s “previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing products like Oxycodone.”<sup>256</sup>

925. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).<sup>257</sup>

926. The Massachusetts Attorney General’s Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

927. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients’ drug use patterns and didn’t use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.<sup>258</sup>

928. On September 30, 2009, the DEA issued an Order to Show Cause against a Walgreens retail facility in San Diego, California based in part on allegations that it was dispensing controlled substances, including opioids, to individuals that it knew or should have

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<sup>255</sup> *Id.*

<sup>256</sup> WAGMDL00021425

<sup>257</sup> *Walgreens to pay \$200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017), <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>.

<sup>258</sup> *Id.*

known were diverting the controlled substances. Although the Order addressed this specific location, the response, including Walgreens's internal assessment of its compliance, or lack thereof, revealed systemic failures from which its County pharmacies would not have been exempt.

929. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 MOA") with the DEA arising from the San Diego OTSC and expressly agreed that it would "maintain a compliance program to detect and prevent diversion of controlled substances as required under the [CSA] and applicable DEA regulations" including regarding the dispensing practices at all of its nationwide pharmacies.

930. On September 14, 2012, however, the DEA also issued an Order to Show Cause and Immediate Suspension Order ("ISO"), described above against Walgreens's Distribution Center in Jupiter, Florida, as well as Orders to Show Cause related to certain Walgreens pharmacies. Evidencing the existence of systemic failures, the ISO stated that, "[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [discussed in the ISO]."

931. The actions against Walgreens as both a distributor and a retail pharmacy demonstrate it routinely, and as a matter of standard operating procedure, violated its legal obligations under the CSA and other laws and regulations governing the distribution and dispensing of prescription opioids.

### **iii. Rite Aid**

932. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.



933. Confirming its systemic failures to implement and adhere to adequate controls against diversion, Rite Aid has repeatedly faced enforcement actions. In addition to those listed in the Third Amended Complaint, as recently as January 2019, it paid \$177,000 into the Naloxone Fund for the State of Massachusetts to resolve allegations that failed to follow regulations designed to prevent substance use disorder in its dispensing of controlled substances, including opioids. Evidencing the systemic nature of the problem, Rite Aid, as part of the agreement, agreed to improve its dispensing practices.

934. In 2018, Rite Aid also agreed to pay a \$300,000 settlement for filling Schedule III controlled substances prescriptions in excess of the maximum dosage units allowed to be dispensed at one time.

935. In 2017, Rite Aid paid \$834,200 in civil penalties to resolve allegations by the DEA that Rite Aid pharmacies in Los Angeles dispensed controlled substances in violation of the CSA. The DEA's "investigation revealed the incorrect or invalid registration numbers were used at least 1,298 times as a result of Rite Aid's failure to adequately maintain its internal database."<sup>259</sup> Further evidencing the lack of internal controls, the settlement also "resolve[d] allegations that Rite Aid pharmacies dispensed, on at least 63 occasions, prescriptions for controlled substances written by a practitioner whose DEA registration number had been revoked by the DEA for cause."<sup>260</sup>

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<sup>259</sup> DEA, Rite Aid Pays \$834,200 Settlement for Alleged Controlled Substances Act Violations in Los Angeles (March 9, 2017), <https://www.dea.gov/press-releases/2017/03/09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act>

<sup>260</sup> *Id.*

936. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.<sup>261</sup>

937. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).<sup>262</sup>

938. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from Chain Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

939. The litany of state and federal actions against the Chain Pharmacies demonstrates that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

940. Throughout the country and in and around Plaintiff's geographical area, the Chain Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

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<sup>261</sup> Press Release, Dep't of Just., *Rite Aid Corporation and Subsidiaries Agree to Pay \$5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act*, U.S. Dep't of Just. (Jan. 12, 2009), <https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations>.

<sup>262</sup> *Id.*

941. On information and belief, from the catbird seat of their retail pharmacy operations, the Chain Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into New Mexico and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

942. On information and belief, the Chain Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

943. On information and belief, because of (among others sources of information) regulatory and other actions taken against the Chain Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Chain Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

944. The Chain Pharmacies’ actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

#### **iv. Walmart**

945. In addition to the actions described above against Walmart, a prosecution against a Virginia prescriber revealed failures at Walmart pharmacies from 2007 to 2012. A Decision and Order in that case revealed that a Walmart pharmacy would fill prescriptions pursuant to a telephone message from a staff member of the prescriber, purportedly on behalf of the prescriber,

even though she failed to provide the prescriber's DEA number. Despite the absence of information required by DEA regulations, the Walmart pharmacy would fill the prescription.<sup>263</sup>

946. By mid-November of 2008, three Walmart pharmacies had dispensed more than 200 hydrocodone prescriptions and refills on behalf of the prescriber. In 2012, the prescriber learned that someone was fraudulently using his DEA number. He called a Walmart pharmacy regarding refill requests faxed from his office, and advised “that somebody was fraudulently using [his] DEA number.”<sup>264</sup> Although he asked that his DEA number be blocked, the same pharmacy still filled two prescriptions on his behalf after this alert. Although Walmart did not face sanctions for its conduct, the Opinion and Order described “the fact that prescriptions which were missing [the] Respondent's DEA number were routinely filling notwithstanding that they were facially invalid,” and “that the prescriptions were for hydrocodone in quantities and dosings that were clearly outside the scope of what is usually prescribed by podiatrists” as “deeply disturbing.”<sup>265</sup>

947. Federal prosecutors had also taken action against five Walmart and Sam's Club Pharmacies in Texas, alleging that they failed to keep records required to help prevent diversion of controlled substances as required by the CSA. Specifically, “accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation of the CSA.”<sup>266</sup> A U.S. Attorney further explained that “[b]ecause of the pharmacies' lack of

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<sup>263</sup> DOJ, DEA, Docket No. 15-26, [FR Doc. No. 2017-13158] Peter F. Kelly, D.P.M.; Decision and Order, <https://www.deadiversion.usdoj.gov/fed regs/actions/2017/fr0623.htm>

<sup>264</sup> <https://www.deadiversion.usdoj.gov/fed regs/actions/2017/fr0623.htm>

<sup>265</sup> *Id.*

<sup>266</sup> Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan 7, 2009), <http://prev.dailyherald.com/story/?id=262762>

proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted.”<sup>267</sup>

948. As recently as September 2018, minutes of an Oklahoma State Board of Pharmacy meeting reflect that an Oklahoma “Wal-Mart Pharmacy was charged with multiple violations of state and federal regulations and rules including establishing and maintaining effective controls against diversion of prescription drugs.”<sup>268</sup> Walmart agreed to pay a fine to resolve the seven alleged violations.

**f. Defendants Performance Metrics Put Profits Before Safety.**

949. Not only did the Chain Pharmacies lack (and fail to implement) adequate policies and procedures to guard against diversion, but CVS, Rite Aid, and Walgreens, and upon information and belief, the other Chain Pharmacies compounded this problem by implementing performance metrics and prescription quotas for retail stores that contributed to supplying of a black market, including in the County.

950. In connection with the DEA’s investigations described above, the DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone.<sup>269</sup> As the DEA’s September 2012 Order to Show Cause and Immediate Suspension of Registration explains:

In July 2010, Walgreens’s corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens’s market pharmacy supervisors in Florida on July 29, 2010, with the admonition that

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<sup>267</sup> *Id.*

<sup>268</sup> <https://www.ok.gov/pharmacy/documents/Min%20September%202018.pdf>

<sup>269</sup> WAGMDL00387654-666 (September 13, 2012 Order to Show Cause and Immediate Suspension of Registration to Walgreens’s Jupiter, Florida Distribution Center).

they “look at stores on the bottom end We need to make sure we aren’t turning legitimate scripts away. Please reinforce.” A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their “busiest store in Florida” was filling almost 18 oxycodone prescriptions per day, yet “We also have stores doing about 1 a day. Are we turning away good customers?”

951. In 2011, a Walgreens project to “Increase Rx Sales and prescription Counts” instructed pharmacies to “improve C2 business” – i.e. dispense more Schedule 2 controlled substances. This focus on increasing controlled substance dispensing – including opioids – continued even after the DEA investigation and \$80 million fine. For example, in 2014, the RX Integrity department created a “Pharmacist Controlled Substance Dispensing Opportunities” tool to “identify pharmacists that are dispensing a low rate of controlled substances,” and help pharmacists “feel more comfortable in filling controlled substances,” specifically focusing on pharmacists dispensing low rates of opioids like “hydromorphone, oxycodone, methadone... hydrocodone,” and the cocktail drugs comprising the rest of the “holy trinity” of abuse, such as “carisoprodol... [and] alprazolam.”

952. Walgreens also had a bonus program that factored prescription volume into bonus calculations, and served as an incentive for pharmacies and pharmacy technicians to ignore the “red flags” of diversion. The corporate push for speed (or volume) deterred pharmacists from taking the time to properly examine the prescriptions before them and exercising their corresponding responsibility to prevent diversion.

953. Walgreens emphasized in its policies for pharmacist and pharmacy managers: “The best evidence of a well-run pharmacy is the increase in prescriptions and pharmacy sales.” One former Walgreens pharmacist described management critiques for “not going fast enough” in dispensing prescriptions and believed “[t]hey’d like you to fill one a minute if you could.” She

recalled there was even a timer to alert her if she was falling behind, and threats of reduced hours or a move to a different store or location. Indeed, Walgreens had a tool, the “PhLOmometer” that tracked the time to fill a prescription. A March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an “[a]nticipated question” that “GFD concerns doesn’t relieve you from trying to attain the numbers that have been set for you.” When considering high schedule 2 dispensing at a particular pharmacy in New Jersey in 2012, as the opioid crisis raged, the pharmacy supervisor pushed back against any attempt to reduce supply of oxycodone, focusing on the impact the reduction would make on filled prescriptions and “the bonus tied to” one pharmacy employee.

954. As described further below, pharmacists were expected to meet volume and speed goals. With respect to the volume-based bonus policy, a March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an “[a]nticipated question” that “GFD concerns doesn’t relieve you from trying to attain the numbers that have been set for you.”

955. Only as part of its 2013 settlement with the DEA, did Walgreens agree to exclude controlled substances calculations from bonus calculations from 2014 forward. This resulted in a 21% reduction in the number of stores purchasing the 80mg OxyContin – evidence that a minimal effort to implement common sense controls had a tangible impact on sales of the most potent controlled substances (although that reduction did not last, as described above, and Walgreens’s volume by 2014 had increased again).

956. Walgreens also lobbied against imposition of caps or limits on the volume of prescriptions a pharmacist may fill. As the New York Times recently reported, pharmacists at

chain pharmacies, including Walgreens have “said it had become difficult to perform their jobs safely, putting the public at risk of medication errors,” as they “struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients, and call doctors and insurance companies ... all the while racing to meet corporate performance metrics that they characterized as unreasonable and unsafe ...”<sup>270</sup> Instead of reducing performance targets, chain pharmacies including Walgreens seek to assign more dispensing tasks to less qualified – and less expensive – pharmacy technicians.

957. CVS used performance metrics related to its own profits, which would rely, in part, upon the number of prescriptions dispensed. By 2010, CVS had implemented performance metrics that remain publicly available online. CVS’s metrics system lacked any measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, including by requiring pharmacists to meet wait- or fill-time expectations. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. Opioid prescriptions were even included in the volume goals until 2013, and after that time, the pressure from the metrics’ focus on profitability remained. These policies remained in place even as the epidemic raged. Opioid prescriptions were even included in the volume goals until 2013, and after that time, the pressure from the metrics’ focus on profitability remained. Even in 2020, pharmacists described CVS as the “most aggressive chain in imposing performance metrics.”<sup>271</sup>

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<sup>270</sup> See Ellen Golbler, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, New York Times, Jan. 31, 2020.

<sup>271</sup> Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), <https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html>



958. As noted above, former pharmacists at both Walgreens and CVS have publicly complained about pressure to put speed ahead of safety. Concerning the metrics at CVS, one pharmacist commented that “You get stressed, and it takes your mind away from the actual prescriptions.” Another former CVS pharmacist recalled that “[e]very prescription [wa]s timed,” and a backlog would pop up in color on pharmacists computer screens if they fell behind.<sup>272</sup> Additionally, CVS has faced discrimination complaints alleging that the company’s “Metrics” system set unobtainable goals — or at least, goals that could not be obtained without violating the laws and practice rules governing pharmacists’ professional responsibilities, edging out older pharmacists.

959. More recently, a former CVS pharmacist in North Carolina described being driven to leave his position and open his own pharmacy, where he could work safely.<sup>273</sup> He described working a 13-hour shift with no breaks for lunch or dinner at CVS the day before he left in December 2018; a day on which he filled “552 prescriptions — about one every minute and 25 seconds — while counseling patients, giving shots, making calls and staffing the drive-through.”<sup>274</sup> In departing, he let his manager know that he would not “work in a situation that is unsafe.”<sup>275</sup> One pharmacist was so alarmed that he wrote anonymously to the Texas State Board of Pharmacy to caution: “I am a danger to the public working for CVS.”<sup>276</sup> It is difficult to

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<sup>272</sup> Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, <http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html>

<sup>273</sup> Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), <https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html>

<sup>274</sup> *Id.*

<sup>275</sup> *Id.*

<sup>276</sup> *Id.*

contemplate how any pharmacist could and/or would be able to meaningfully comply with any corporate policy regarding red flag analyses or any anti-diversion analysis under such draconian pressures.

960. Walgreens and CVS were not alone in this regard. As described above, Rite Aid had performance metrics in place that exacerbated its failures. Without describing individual pharmacies, Daniel Hussar, a nationally-known expert and teacher of pharmacology at Philadelphia's University of the Sciences, commented in the media that the pace and pressure of prescription quotas appeared to be having an impact on accuracy. "The frequency of these errors is increasing greatly," Hussar said; "I've heard some pharmacists say, 'It's a blur as to what happened during the day and I can only pray I didn't make any serious mistakes.'"<sup>277</sup>

961. This pressure and focus on profits would not only lead to mistakes, it also would necessarily deter pharmacists from carrying out their obligations to report and decline to fill suspicious prescriptions and to exercise due care in ascertaining whether a prescription is legitimate.

962. Indeed, "a survey by the Institute for Safe Medication Practices (ISMP) revealed that 83% of the pharmacists surveyed believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, as well as that 49% felt specific time measurements were a significant contributing factor."<sup>278</sup>

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<sup>277</sup> *Are Business Tactics at Some Pharmacies Risking Your Health?*, ReachMD citing ksdk.com (Nov. 8, 2017), <https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/>.

<sup>278</sup> NAPB, *Performance Metrics and Quotas in the Practice of Pharmacy* (Resolution 109-7-13) (June 5, 2013), <https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/>.

963. In 2013, the National Association of Boards of Pharmacy (NABP), passed a resolution which cited this survey and additionally stated that “performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment” and “the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists’ ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy.”<sup>279</sup>

964. Still, according to a 2016 investigation by the Chicago Tribune, as chain pharmacies increasingly promote quick service, “pharmacists frequently race through legally required drug safety reviews — or skip them altogether,” missing dangerous drug combinations in the process.<sup>280</sup> A pharmacist too rushed to check for a potentially deadly drug interaction is also likely to be too rushed to check for red flags of diversion, such as prescription “cocktails” or other combinations of highly abused drugs.

965. According to the *Tribune*’s coverage, “Wal-Mart, operator of 4,500 U.S. pharmacies, failed 43 percent of its tests.”<sup>281</sup> Walgreens, meanwhile, failed a test of whether pharmacists would dispense dangerous drug combinations without warning patients 30 percent

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<sup>279</sup> *Id.*

<sup>280</sup> Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, <http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html>.

<sup>281</sup> *Id.*

of the time.<sup>282</sup> Further, a Walmart pharmacist commented that she typically filled 200 prescriptions in her daily nine-hour shift, and an even higher volume when working at a different store, equating to two prescriptions per minute.<sup>283</sup>

966. In reporting on the results of its investigation, the *Tribune* quoted Bob Stout, president of the New Hampshire Board of Pharmacy, stating that ““They’re cutting corners where they think they can cut.”<sup>284</sup> As the report itself explained: “some pharmacies emphasize fast service over patient safety. Several chain pharmacists, in interviews, described assembly-line conditions in which staff hurried to fill hundreds of prescriptions a day.”<sup>285</sup>

967. More recently, a January 2020 New York Times article, referenced above, revealed that the problematic performance metrics remain, and have remained, in place. One South Carolina pharmacist advised:

We are being asked to do things that we know at a gut level are dangerous. If we won’t or can’t do them, our employers will find someone else who will, and they will likely try to pay them less for the same work.

968. In March 2020, journalists also revealed that Walmart not only ignored reports of suspicious activity from pharmacists concerned that they were filling prescriptions for pill mills, but the company considered these pharmacists’ focus misdirected. One internal email, reviewed by ProPublica, showed that in response to a question from a regional manager in 2015 about documenting pharmacists’ concerns about doctors believed to be operating pill mills, Walmart’s director of Health and Wellness Practice Compliance, Brad Nelson, wrote that “We have not

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<sup>282</sup> *Id.*

<sup>283</sup> *Id.*

<sup>284</sup> *Id.*

<sup>285</sup> *Id.*

invested a great amount of effort in doing analysis on the data since the agreement [requiring such reporting] is virtually over. Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time.<sup>286</sup>

969. As described above, Walmart refused to allow pharmacies to flag and block all prescriptions from doctors whose prescriptions raised red flags that they were running pill mills. Not only did pharmacists have to refuse each prescription individually, to do so, "a pharmacist had to fill out a form that could take 20 minutes, a bureaucratic hurdle that pharmacists sought to avoid because they were under pressure to fill prescriptions quickly."<sup>287</sup>

**g. Defendants Worked Together to Increase Their Profits and Lobbied Against Restrictions on Opioid Use and DEA Enforcement.**

970. The DEA's suspensions of the registrations of three major distributors in 2007, lit a fuse within the industry. The very real threat of DEA enforcement prompted a flurry of communications between NACDS members and members of the HDA, described above, as well as the now-notorious Pain Care Forum ("PCF"), a forum run by opioid manufacturers. A goal of HDA, which it shared with NACDS, was to "develop a comprehensive DEA strategy" to avoid enforcement actions against distributors.

971. The NACDS and Defendants' other trade groups saw their role in influencing diversion policy as being one that was absolutely critical, considering all that was at stake. At times, these groups adopted militaristic strategies, and used terminology ironically similar to the "War on Drugs," developing "task forces" and viewing the DEA's crackdown on distributors and

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<sup>286</sup> Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), <https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment>

<sup>287</sup> *Id.*

chain pharmacies as an assault on the companies themselves. Only this time, the war was being waged against the very regulatory authorities and government entities fighting to deal with the ever-growing problem of abuse and diversion in this country.

972. Manufacturers' participation in Defendants' trade groups as a means to effectuate favorable policies is clear when evaluated in the context of how Defendants and other stakeholders viewed the DEA's attempts to curb the opioid epidemic.

973. Walgreens and the other Defendants recognized the importance of controlling and influencing trade groups such as the NACDS in the context of influencing policy related to opioid drug abuse and diversion. The efforts taken by the NACDS and other trade groups on behalf of Defendants were so important to their bottom line that Defendants spared no expense in supporting such groups. Walgreens took a particularly aggressive view of this mutually beneficial relationship, at times, being its top donor across the country.

974. NACDS worked with the HDA, the Alliance to Prevent the Abuse of Medicines ("APAM"), and the PCF to support the Marino Blackburn Bill, also known as S.483 or the "Marino Bill. NACDS, and Defendants intended the Marino Bill to "tie the hands" of the DEA to actively and aggressively address diversion and compliance with the CSA." NACDS worked together with others in opioid supply chain to influence the language in the bill to make it most favorable for them and more restrictive on the DEA. Notably, masking the influence of industry, when the APAM was asked to sign on to a 2014 letter of support it was "signed by the Alliance, *not the individual members.*" The final letter that was sent to Senators Hatch and Whitehouse was signed by the members of the Pain Care Forum as well as the Alliance, the NACDS, American Academy of Pain Management, and U.S. Pain Foundation.

975. The Marino Bill effectively removed the DEA's ability to issue immediate suspension orders regarding manufacturer or distributor registrations. The Marino Bill permitted a non-compliant registrant an opportunity to cure its noncompliance before the DEA could take enforcement action and changed the standard upon which revocation occurred. In the midst of a growing opioid crisis, the Marino Bill removed the most effective deterrent and constrained DEA enforcement actions.

976. With respect to its efforts to tie the hands of the DEA in its ability to pursue and hold accountable Defendants and other stakeholders for violations of law related to the sale and distribution of prescription opioids, CVS appreciated NACDS's influence.

977. CVS as a member of the HDA, NACDS and the APAM was actively involved in efforts to curb the enforcement power of the DEA in its support of the Marino Bill. Its history and ties to the HDA and NACDS run deep.

978. The APAM is a trade group launched in the fall of 2013 and comprised of members of the American Medical Association, Cardinal, CVS, HDMA, Prime Therapeutics and Teva Pharmaceuticals.

979. CVS and Defendants used trade groups like the HDA, NACDS and APAM to gain favorable results when it came to regulations and roadblocks that were seen as being in the way of the Defendants ability to capitalize on the opioid business. In particular CVS would often hide behind the APAM when it knew its position could be controversial as it related to abuse and diversion. This particular letter was one in support of the controversial Marino Bill, a bill that CVS fought hard to push through, supporting it on three different fronts.

980. In August of 2011, NACDS worked with others on a joint letter opposing DEA fee increases for registrants that were intended to fund the “hir[ing of] more agents and do[ing] more inspections.”

981. HDA’s Crisis Handbook, developed in 2013, was a direct response to the “threats” perceived by HDA’s members and affiliates, including Defendants, to their bottom line: profits derived from the distribution and sale of prescription opioids.<sup>288</sup> Defendants, did and continue, to rely on and employ the strategies discussed in the Crisis Playbook. Curiously, there are no slides on how best HDA and its members, including Defendants, might work to curb the crisis that is the opioid epidemic.

982. In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their state drug monitoring program before filling controlled prescriptions.<sup>289</sup> NACDS also fought regulatory efforts to require Defendants to use available dispensing related data and red flags to prevent diversion, opposing what it described as “recent DEA actions in which DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications.

983. NACDS and HDA sought to slow down and impede DEA enforcement activities by requiring the DEA to “work with the [Food and Drug Administration] FDA on all drug diversion issues,” ostensibly on the grounds that the DEA’s diversion enforcement activities – including “clos[ing] drug distribution centers and pharmacies” and “actions against pharmacies”

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<sup>288</sup> ABDCMDL00278063.

<sup>289</sup> WAGMDL00605718 (including Walgreens & Walmart).



were harmful in ““leading to patients not being able to receive their medications.” This purported concern, however, was industry code for impediments to sales.

984. NACDS and HDA agreed that the pharmacies should “be more aggressive” and “lead the charge” with respect to certain DEA issues. NACDS members coordinated regarding pharmacy diversion and “DEA red flags” through a “DEA Compliance Workgroup.” Defendants further used a NACDS “Pharmacy Compliance Roundtable” to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion. And, in May 2012, the NACDS formed a Policy Council “Task Group” to “discuss issues and develop strategies” concerning “ongoing problems that NACDS members are having with DEA enforcement actions,” through which it sought to influence the government and media, set meetings with legislators seeking to “address the problems with DEA actions,” and “collaborate with, and support others’ efforts” including HDA.

**h. Defendants Also Entered Into Joint Ventures that Further Undermined their Outside Vendors Incentive to Conduct Due Diligence, While Increasing their Own Access to Information.**

985. The collaboration between Defendants and other industry partners extended beyond their mutual interest in limiting regulations and enforcement that constrained their ability to sell opioids. Indeed, the companies had direct financial relationships that, quite literally, invested them in each other’s success.

986. As described above, Walgreens entered into an exclusive arrangement with AmerisourceBergen as its supplier, with Walgreens obtaining both equity in AmerisourceBergen and a seat on its Board. As part of a three-year extension of that arrangement, in 2016, two agreed to include a requirement that AmerisourceBergen “make certain working capital investments in the relationship and will proceed with additional capital investments in its distribution network.”

987. The merger between Walgreens and AmerisourceBergen had begun in 2012, when the two formed Walgreens Boots Alliance Development, a joint venture based in Switzerland. AmerisourceBergen was described as being able to gain from Walgreens's "purchasing synergies," through the companies' relationship.

988. In 2014, CVS entered into a 50/50 joint venture with Cardinal to create Red Oak Sourcing, LLC ("Red Oak"). Red Oak uses the combined generic purchasing power of CVS and Cardinal to negotiate with generic drug manufacturers, and its website touts its management of a "multi billion dollar pharmaceutical portfolio." To fund the venture, Cardinal would make quarterly payments of \$25.6 million to CVS, and also would contribute additional funds if the joint venture reached certain milestones.

989. In 2016, McKesson and Walmart formed ClarusOne Sourcing Services LLP to source generic pharmaceuticals for their respective U.S. operations. As part of this "partnership," McKesson and Walmart "established an organization in London to provide strategic sourcing services for both companies," according to a job posting on McKesson's website.

990. Given that Walgreens, CVS, Walmart, on the one hand, the largest wholesalers, on the other, considered themselves partners invested in one another's success, they had even less incentive to turn away from the blind deference the Chain Pharmacies received when buying and selling controlled substances.

**i. Defendants Worked With Opioid Manufacturers to Promote Opioids and Bolster Their Profits at the Expense of Communities Like the County.**

991. Defendants also worked in concert with opioid manufacturers to ensure that the false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders.

992. For example, as early as 2001, CVS worked closely with Purdue and its un-branded marketing arm, Partner's Against Pain ("PAP") to "fight back" against allegations (later proved to be true) that Purdue's Oxycontin was being abused at alarming rates. It was Purdue's Partner's Against Pain website that Purdue, and its "Partners" including CVS, utilized to make the claims that the risk of addiction associated with Oxycontin was very small.

993. Purdue worked together with CVS to ensure that CVS's own pharmacists were trained by Purdue on many of the misleading marketing messages that would later form the basis for a 2007 criminal guilty plea and \$600 million fine between Purdue the Department of Justice for misleading regulators, doctors, and patients about Oxycontin's risk of addiction and its potential for abuse. CVS's ties to PAP were so deep that CVS even went so far as to put CVS's own logo communications from its "partner".

994. CVS was so eager to ally itself with Purdue that it solicited Purdue for its participation in co-hosting Continuing Education ("CE") programs for healthcare providers and pharmacists regarding training on diversion of prescription opioids.

995. One would have to seriously question the accuracy of any training CVS pharmacists received from Purdue and Partners Against Pain on abuse and diversion, yet there has been no evidence provided by Defendants that CVS undertook any measures to re-educate its pharmacists on how or why Purdue and PAP training might be lacking in the area of diversion and abuse of opioids.

996. CVS's role was not limited to expanding the market for prescription opioids. CVS worked hard to ensure that demand for prescription opioids was not only sustained but multiplied. It did so through its marketing, advertising, and promotional efforts both on its own and in concert with other stakeholders

997. Contrary to what CVS claims, CVS helped to grow the demand for prescription opioids and contributed to the public nuisance by participating in the marketing, advertising, and promotion of opioid products with and on behalf of the opioid manufacturers.

998. CVS's marketing and promotion of opioids was not limited to its involvement with Purdue and Partners Against Pain. CVS did not draw lines when it came to promoting opioids, and there were no brand boundaries.

999. One example can be found in CVS's work with Endo Pharmaceutical ("Endo") to increase patient adherence to continuing their use of opioids. In fact, CVS played such an important part in the promotion of Endo's Opana ER, that it was included as having a crucial role in carrying out one of key sales tactics included in Endo's 2012 Business Plan.

1000. Through a company called Catalina Health ("Catalina"), Endo was able to target Oxycontin patients in areas where Opana ER, a highly abused opioid manufactured by Endo, had preferred formulary status. Catalina in turn worked to create a brand loyalty program that kept new patients on their opioids. CVS, through its pharmacy retention programs, sent letters to the patients' homes to encourage them to stay on Opana – even though prolonged use of opioids

1001. increases the risk of addiction, and even though patients in pain presumably need no reminder to continue to take their pain medications. CVS formalized its agreement to promote, market and advertise Endo's opioid products via its "CVS Carecheck Plus Patient Education Service." Under this Agreement, CVS not only contractually agreed to promote Opana ER to its customers (patients) at the point of sale, but it even insisted upon reviewing and approving the specific messaging used.

1002. Similarly, CVS contracted with manufacturers like Endo to prepare and disseminate materials promoting Opana ER nationwide.

1003. CVS likewise helped Actavis promote its opioids by participating with Cardinal's Marketing and Business Development team in programs designed to offer rebates and off-invoice discounts on products, with the aim being to "move [] product."

1004. Marketing, advertising, and promoting opioids was not a new practice for CVS. In fact, CVS had been advertising these services to manufactures for years. For example, CVS made at least one pitch to Insys, a company whose senior executives were recently criminally convicted for their unlawful marketing, to help sell its incredibly potent opioid, Subsys, a liquid form of fentanyl.

1005. CVS touted the reach of its communications and explained the science behind its sophisticated marketing, advertising, and promotional services.

1006. Hardly novices, CVS recognized its expertise in ensuring that opioid manufacturers like Insys were able to reach their intended market by using CVS's promotional programs which are designed to "deliver results."

1007. Through CVS's NEWScript program, CVS claimed to be perfectly poised to assist with new product launches and described its truly impressive reach.

1008. CVS even offered Insys the chance at having a literature display in its patient waiting rooms and to help Insys "target patients" using its signature ExtraCare consumer loyalty card database.

1009. Working with Purdue as early as 2001, Walgreens played a pivotal role in expanding the market and ensuring the demand and supply for prescription opioids would grow exponentially. Purdue was particularly interested in using what Walgreens described to Purdue as its Regional Level Market Programs to educate pharmacists and patients on the benefits of Purdue's OxyContin.

1010. In fact, Purdue leveraged its relationship with Walgreens and their mutually beneficial goal of growing the opioid business to ensure that Purdue had input into Walgreens “corporate guidelines” to which Walgreens pharmacists were “expected to follow” when it came to the dispensing of prescription opioids.

1011. Walgreens also used its corporate oversight abilities to identify stores it believed were not filling enough oxycodone to make sure they weren’t “turning away good customers” and encouraging stores to utilize CE created by opioid manufacturers to inform their decisions regarding dispensing.

1012. Starting in at least 1999, Purdue sponsored Walgreens’s Pharmacy CE programs designed to encourage stores to “get on the Pro Pain Management Band Wagon.” Purdue was thrilled with the response and assistance it received from Walgreens when Purdue presented on “Pain Management for the Pharmacist.” At the beginning of each Purdue sponsored meeting, a Walgreens pharmacist made a presentation on his store and the program implemented. His store actively advertised to area doctors and patients that they were a “full- service” pain management pharmacy. This service included providing a list to physicians’ offices of all CIIIs they had in stock (and they had everything), accepting “verbal orders” for Class II analgesics prior to presentation of the original prescription at the store to decrease “waiting time”, allowing partial fills on CII prescriptions in terminal patients, and accepting after hours “emergency CII prescriptions” without a hassle. Purdue praised the pharmacist’s actions as “fantastic”.

1013. Walgreens’s use of pro-opioid CE continued as the opioids crisis grew. For example, Walgreens’s Market Director of Pharmacy Operations recommended that Walgreens District Managers and Pharmacy Supervisors attend a CE program titled “The Pharmacists’ Role in Pain Management: A Legal Perspective,” which was available on-line at RxSchool.com. This

program was one in a long line of pharmacist “education” programs, or CEs, that opioid manufacturer Purdue developed as part of its strategy to disseminate “a new school of thought” about opioids. Through these programs, Purdue and the Chain.

1014. Pharmacies disseminated fraudulent information that redefined the red flags of abuse or diversion in an effort to correct pharmacists’ “misunderstanding” about pain patients and the practice of pain management. Purdue took what it called an “aggressive role” in the education of Walgreens’s and other pharmacists on pain management issues.

1015. Walgreens’s Market Director of Pharmacy Operations also recommended a second continuing education program titled “Navigating the Management of Chronic Pain: A Pharmacist's Guide.” The second “CE” incorporated into Walgreens’s dispensing training program, “Navigating the Management of Chronic Pain: A Pharmacist's Guide” was sponsored by opioid manufacturer Endo Pharmaceuticals and disseminated manufacturer messaging designed to broaden the market for opioids. For example, it stated, “according to most reports, approximately 30% of the population lives with chronic pain” and citing, *inter alia*, another CE presentation sponsored by the American Pain Society (another known front-group). It also claimed that “most opioid adverse effects can be managed with careful planning and patient education.” It went on to discuss “fears and prejudices” related to addictive behaviors that “unnecessarily limit” opioid use, described as “opiophobia” which the piece claimed was the result of “misunderstandings regarding the concepts of addiction, physical dependence, and tolerance.”

1016. One of the presenters for this Endo sponsored CE was Kenneth C. Jackson. Mr.

1017. Jackson was a frequent speaker and KOL for Purdue. Mr. Jackson also co-authored the CE program titled “Use of Opioids in Chronic Noncancer Pain”, which was

sponsored by Purdue. Released in April 2000, it was designed to eliminate “misconceptions about addiction, tolerance and dependence” and contained many of the same messages as the pharmacist guide he authored.

1018. Walgreens also presented the video, The Pharmacist’s Role in Pain Management - A Legal Perspective at mandatory meetings for pharmacy managers. This CE was also sponsored by Purdue, was similar to the earlier presentations, and was further disseminated to Walgreens pharmacists in June 2011. Released in 2009, the program was presented by Jennifer Bolen, JD. Ms. Bolen was a frequent speaker for Purdue and other opioid manufacturers, served as Special Counsel for the American Academy of Pain Medicine (a known front group for opioid manufactures), acted as a KOL for Purdue, and was described by Purdue as “a pain patient who takes opioids”.

1019. Armed with information gleaned from Purdue sponsored CE, the Walgreens pharmacists who had temporarily stopped filling controlled substances prescriptions began to accept them again. It is no surprise that in 2013 Walgreens acknowledged that several of the stores that touted this CE as part of their controlled substance action plan dispensed “certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA.”

1020. Rite Aid likewise helped to expand the market and increase the demand for prescription opioids by working in concert with manufactures like Purdue. Capitalizing on Rite Aid’s reach, Purdue worked with Rite Aid as early as 2001 to promote its highly addictive, OxyContin. The return on investment of such a program was clear to both Purdue and Rite Aid.

1021. Both Purdue and Rite Aid recognized the importance of a chain pharmacy and pharmacists in the efforts to expand and sustain the demand for prescription opioids. Purdue



memorialized its observation that as the last line of defense, our pharmacists at the retail level” were the “most important audience. . . in highly sensitive areas” – presumably those already impacted, even in 2001, by the opioid epidemic.

**j. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement.**

1022. When a distributor does not report or stop suspicious orders, or a pharmacy fails to maintain effective policies and procedures to guard against diversion, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

1023. Despite their conduct in flooding states with dangerous and unreasonable amounts of opioids, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion.

1024. In its 2011 MOA, Walgreens agreed to undertake several different anti-diversion measures. Yet, as a DEA official explained in a subsequent Order to Show Cause and Immediate Suspension of its registration that was issued a mere month later and pertained to Walgreens’s Jupiter Florida Distribution Center, Walgreens’s “anti-diversion” measures appeared to be primarily self-serving:

[W]hen a company undertakes to survey its stores for regulatory compliance, then selectively edits that survey for the explicit purpose of avoiding evidence of its own non-compliance, as Walgreens apparently did in May 2011, claims of effective remedial measures have less credibility. I gave significant weight to the fact that Walgreens appears to have deliberately structured certain of its antidiversion measures to avoid learning about and/or documenting evidence consistent with diversion. At best, I regard this as deliberate indifference on Walgreens’[s] part as to its obligations as a DEA registrant.

My confidence in Walgreens'[s] remedial measures is lessened further by the fact that this manipulation of the compliance survey occurred just one month after Walgreens entered into a nationwide Memorandum of Agreement (MOA) with DEA to resolve an Order to Show Cause issued to a San Diego Walgreens pharmacy based on allegations of unlawful dispensing. . . . Walgreens'[s] effort to enact . . . [a compliance] program in Florida appears to have been, in part, intentionally skewed to avoid actually detecting certain evidence of possible diversion.

1025. Despite the behavior described above, Walgreens nevertheless publicly portrayed itself as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs.

1026. In August of 2018, after journalists at the Washington Post disclosed information gleaned from the ARCOS data regarding the staggering number of opioids Walgreens distributed and sold, Walgreens again publicly promoted itself as being and “ha[ving] been an industry leader in combatting this crisis in the communities where our pharmacists live and work.” Walgreens further asserted that “Walgreens pharmacists are highly trained professionals committed to dispensing legitimate prescriptions that meet the needs of our patients.”<sup>290</sup>

1027. Yet, in January 2020, Walgreens released a Board Report on Oversight of Risks Related to Opioids. There, it claimed that: “In recent years, the Company has implemented a number of operational changes that it believes have helped to reduce its risk with respect to its dispensing of prescription opioids. The Company is focused on the continuous improvement of its controlled substances compliance program, implementing enhancements to prevent, identify

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<sup>290</sup> Aaron C. Davis & Jenn Abelson, *Distributors, pharmacies and manufacturers respond to previously unreleased DEA data about opioid sales*, Washington Post (Aug. 8, 2019), [https://www.washingtonpost.com/investigations/distributors-pharmacies-and-manufacturers-respond-to-previously-unreleased-dea-data-about-opioid-sales/2019/07/16/7406d378-a7f6-11e9-86dd-d7f0e60391e9\\_story.html](https://www.washingtonpost.com/investigations/distributors-pharmacies-and-manufacturers-respond-to-previously-unreleased-dea-data-about-opioid-sales/2019/07/16/7406d378-a7f6-11e9-86dd-d7f0e60391e9_story.html)

and mitigate the risk of non-compliance with federal and state legal requirements.”<sup>291</sup> It went on to tout its “Good Faith Dispensing policy,” as “provid[ing] the foundation for our pharmacists to understand their roles and responsibilities when dispensing prescriptions for controlled substances.”<sup>292</sup> It also claimed that “the Company conducts its own voluntary, independent review of controlled substance purchase orders placed by our pharmacies, providing an additional layer of review above and beyond the legally required monitoring performed by the wholesalers.”<sup>293</sup> There, Walgreens’s Board acknowledged that the “fundamental elements of an effective compliance program include,” among other things, “[w]ritten policies, procedures, and standards of conduct setting forth the Company’s expectations and requirements for operating all business activities in an ethical and compliant manner”; “[o]versight of the Compliance Program by the Global Chief Compliance and Ethics Officer, Compliance and Ethics Officers for each operating division, and Compliance and Governance Committees”; and, “[a]uditing and monitoring.”<sup>294</sup>

1028. With respect to compensation, the Board stated: “[w]e have a strong pay-for-performance philosophy.” Accordingly, its “Compensation and Leadership Performance Committee,” the Board explained, “aims to incent leaders to support the Company’s culture and model desired behaviors, ensuring ethical behavior and mitigating risks, through ongoing monitoring, reviewing and governance of all incentive plans.”<sup>295</sup>

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<sup>291</sup> [https://s1.q4cdn.com/343380161/files/doc\\_downloads/governance\\_guidelines/Board-Report-on-Oversight-of-Risk-Related-to-Opioids-June-2019-rev.-August-2019.pdf](https://s1.q4cdn.com/343380161/files/doc_downloads/governance_guidelines/Board-Report-on-Oversight-of-Risk-Related-to-Opioids-June-2019-rev.-August-2019.pdf)

<sup>292</sup> *Id.*

<sup>293</sup> *Id.*

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*

1029. Yet, at the end of January 2020, the New York Times revealed that Walgreens had not reformed its policies putting speed ahead of safety and pharmacists continued to feel pressed to do more with less. According to the article, pharmacists at Walgreens and Rite Aid stores “described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs safely, putting the public at risk of medication errors.”<sup>296</sup> The article explained that these pharmacists “struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients and call doctors and insurance companies,” while “racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less.”<sup>297</sup>

1030. Citing company documents, the article showed that Walgreens continue to tie bonuses to achieving performance metrics. Walgreens, in response stated that errors were rare and that “it made ‘clear to all pharmacists that they should never work beyond what they believe is advisable.’”<sup>298</sup> Similarly, CVS assured that “[w]hen a pharmacist has a legitimate concern about working conditions, we make every effort to address that concern in good faith.”<sup>299</sup>

1031. Meanwhile, the New York Times’ coverage disclosed that a CVS form for staff members to report errors internally asked whether the patient poses “a ‘media threat.’”<sup>300</sup> According to the article, “[t]he American Psychiatric Association is particularly concerned about CVS, America’s eighth-largest company, which it says routinely ignores doctors’ explicit

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<sup>296</sup> Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), <https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html>

<sup>297</sup> *Id.*

<sup>298</sup> *Id.*

<sup>299</sup> *Id.*

<sup>300</sup> *Id.*

instructions to dispense limited amounts of medication to mental health patients.”<sup>301</sup> The group’s president further observed that “[c]learly it is financially in their best interest to dispense as many pills as they can get paid for[.]”

1032. Following its Texas settlement, Walmart claimed that the agreement pertained to a small number of stores in that state and claimed that Walmart was “eager to comply with the law.”<sup>302</sup> A Walmart spokesperson further claimed that: “We take record keeping seriously[.]” and “[w]e continuously review our processes at our pharmacies to ensure they are accurate and in full compliance with the law.”<sup>303</sup>

1033. More recently, Walmart reportedly claimed to be cooperating with a federal investigation and “taking action to fix its opioid dispensing practices.”<sup>304</sup> In fact, however, Walmart subsequently “acknowledged that it halted its cooperation in mid-2018.”<sup>305</sup>

1034. Rite Aid similarly claims to be committed to working with “both federal and state agencies to help reduce the opioid epidemic that is impacting our communities throughout the United States.”<sup>306</sup>

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<sup>301</sup> *Id.*

<sup>302</sup> Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan 7, 2009), <http://prev.dailyherald.com/story/?id=262762>

<sup>303</sup> *Id.*

<sup>304</sup> Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, *ProPublica*, (March 25, 2020), <https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment>

<sup>305</sup> *Id.*

<sup>306</sup> Rite Aid, Pharmacy, Health Information, <https://www.riteaid.com/pharmacy/health-information>

1035. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, all Defendants through the joint amicus brief filed by the HDMA and NACDS in *Masters Pharmaceuticals*, described above, made the following statements:<sup>307</sup>

“HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”

“Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.”

1036. Through the above statements made on their behalf by their trade association, and other similar statements assuring its continued compliance with their legal obligations, Defendants not only acknowledged that they understood their obligations under the law, but further affirmed that their conduct was in compliance with those obligations. In doing so, Defendants further delayed efforts to address the growing opioid epidemic.

1037. Through the above statements and others, Defendants not only acknowledged that they understood their obligations under the law, but created the false and misleading impression that their conduct was in compliance with those obligations.

**F. The Opioids the Defendants Sold Migrated into Other Jurisdictions**

1038. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state lines in a variety of ways.

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<sup>307</sup> Brief for HDMA and NACDS, 2016 WL 1321983, at \*3-4, 25.

1039. First, prescriptions written in one state may, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them.

1040. When authorities in states such as Ohio and Kentucky cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals “prescription tourists.”

1041. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren county, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as \$100 a pill—ten times the pharmacy price.<sup>308</sup> In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the “oxycodone pipeline between Ohio and Florida.”<sup>309</sup> When officers searched the Ohio home of the alleged leader of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone, and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same

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<sup>308</sup> Andrew Welsh-Huggins, *‘Prescription tourists’ thwart states’ crackdown on illegal sale of painkillers*, NBC News (July 8, 2012), [http://www.nbcnews.com/id/48111639/ns/us\\_news-crime\\_and\\_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71](http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71).

<sup>309</sup> *16 charged in ‘pill mill’ pipeline*, Columbus Dispatch (June 7, 2011), <http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html>.

conduct—paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. district judge Michael Watson, contributing to a “pipeline of death.”<sup>310</sup>

1042. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 for operating a pill mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other states, including North Carolina, Kentucky, Tennessee, Ohio, South Carolina, and Florida.<sup>311</sup> Another investigation in Atlanta led to the 2017 conviction of two pharmacists who dispensed opioids to customers of a pill mill across from the pharmacy; many of those customers were from other states, including Ohio and Alabama.<sup>312</sup>

1043. In yet another case, defendants who operated a pill mill in south Florida were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the PCB’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio, Georgia, and Massachusetts.”<sup>313</sup> The court further noted that the pill mill

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<sup>310</sup> *Leader of Ohio pill-mill trafficking scheme sentenced*, Star Beacon (July 16, 2015), [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article\\_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html).

<sup>311</sup> *Four Defendants Plead Guilty to Operating a “Pill Mill” in Lilburn, Georgia*, U.S. Atty’s Off., Northern District of Ga. (May 14, 2015), <https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia>.

<sup>312</sup> *Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill*, U.S. Atty’s Off., Northern District of Ga. (Mar. 29, 2017), <https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill>.

<sup>313</sup> *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).



“gained massive financial benefits by taking advantage of the demand for oxycodone by Kentucky residents.”<sup>314</sup>

1044. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt.<sup>315</sup> Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag.<sup>316</sup> If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over.<sup>317</sup> Or they avoided the roads altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so popular with drug couriers that it was nicknamed the “Oxy Express.”<sup>318</sup>

1045. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.<sup>319</sup>

1046. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from

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<sup>314</sup> *Id.* at 861.

<sup>315</sup> John Temple, *American Pain* 171 (2016).

<sup>316</sup> *Id.*

<sup>317</sup> *Id.*

<sup>318</sup> *Id.*; see also Welsh-Huggins, *supra* n. 1. Note that Interstate 75 is also called the Oxy Express; for example, the Peabody Award-winning documentary by that name focuses on the transport of prescription opioids along I-75.  
<https://www.youtube.com/watch?v=wGZEvXNqzkM>

<sup>319</sup> *Id.*

Florida, Georgia, and California.<sup>320</sup> And, according to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.<sup>321</sup>

1047. Along the West Coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the city of Everett, Washington.<sup>322</sup> Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.<sup>323</sup> The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state.<sup>324</sup>



<sup>320</sup> Nok-Noi Ricker, *Slaying of Florida firefighter in Maine puts focus on Interstate 95 drug running*, Bangor Daily News (March 9, 2012), <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running/>

<sup>321</sup> Julia Smillie, *Michigan's Opioid Epidemic Tackled From All Directions By Detroit FBI*, Workit Health (October 6, 2017), <https://www.workithealth.com/blog/fbi-michigan-opioid-crisis>

<sup>322</sup> Harriet Ryan et al., *How black-market OxyContin spurred a town's descent into crime, addiction and heartbreak*, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-everett/>.

<sup>323</sup> *Id.*

<sup>324</sup> *Id.*

1048. Abundant evidence, thus, establishes that prescription opioids migrated between cities, counties, and states. As a result, prescription data from any particular jurisdiction does not capture the full scope of the misuse, oversupply, and diversion problem in that specific area. As the criminal prosecutions referenced above show, if prescription opioid pills were hard to get in one area, they migrated from another. The manufacturers and distributors were fully aware of this phenomenon and profited from it.

**G. New Mexico-Specific Facts**

1049. The Defendants all marketed their products and disseminated their misrepresentations in the State of New Mexico, and distributed opioids and failed to meet their regulatory obligations in New Mexico.

**1. Defendants Breached Their Duties in New Mexico**

1050. In addition to the duties imposed by federal law, under New Mexico law, distributors have a duty to detect, investigate, refuse to fill, and report suspicious orders of opioids.

1051. New Mexico regulations further mandate that suspicious orders, defined as unusual in size or frequency or deviation from buying patterns, be reported. Any of the red flags identified by law trigger a duty to report, but this list is not exhaustive. Other factors—such as whether the order is skewed toward high dose pills or orders that are skewed towards drugs valued for abuse—also should alert distributors to potential problems.

1052. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply—those observations can also trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an

order that is unusual given the customer's history or its comparison to other customers in the area.

1053. Defendants were required by New Mexico law to operate in compliance with federal laws, including the federal CSA, 21 U.S.C. § 801 *et seq.* and its implementing regulations.

1054. A number of New Mexico counties had an opioid prescription rate exceeding their population for extended periods of time.

1055. Marketing and Distributor Defendants should have been on notice that the diversion of opioids was likely occurring in New Mexico communities, should have investigated, ceased filling orders for opioids, and reported potential diversion to law enforcement.

1056. In addition, the increase in fatal overdoses from prescription opioids has been widely publicized for years. New Mexico has faced a spike in fatal drug overdoses, the majority of which are attributable to prescription opioids or the illicit opioids that patients often began abusing after becoming addicted to prescription opioids. The CDC estimates that for every opioid-related death, there are 733 non-medical users. Marketing and Distributor Defendants thus had every reason to believe that illegal diversion was occurring in Plaintiff's communities.

1057. Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in communities across New Mexico.

1058. Each of the Defendants disregarded their reporting and due diligence obligations under New Mexico law in and affecting the Plaintiff. Instead, they consistently failed to report or suspend illicit orders, deepening the crisis of opioid abuse, addiction, and death in New Mexico.

## 2. The Devastating Effects of the Opioid Crisis in New Mexico

1059. The Marketing Defendants’ misrepresentations prompted New Mexico health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, the Marketing Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. Defendants compounded these harms by supplying opioids beyond even what this expanded market could bear, funneling so many opioids into New Mexico communities that they could only have been delivering opioids for diversion and illicit use.

1060. Marketing Defendants’ deceptive marketing substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

1061. The sharp increase in opioid use resulting from Defendants’ conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in New Mexico. Representing the NIH’s National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that “aggressive marketing by pharmaceutical companies” is “likely to have contributed to the severity of the current prescription drug abuse problem.”

1062. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this “urgent health crisis” and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the “devastating” results that followed, had “coincided with heavy marketing to doctors . . .

[m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain.”

1063. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

1064. By continuing to fill and failing to report suspicious orders of opioids, Defendants have enabled an oversupply of opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids for both patients who could no longer access or afford prescription opioids and individuals struggling with addiction and relapse. Defendants had financial incentives to distribute higher volumes and not to report suspicious orders or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

1065. Individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high.

1066. In fact, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain

medication as the strongest risk factor for heroin addiction. Roughly 80% of heroin users previously used prescription opioids.

1067. A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that has made its way into New Mexico communities.

1068. New Mexico has had one of the highest rates of drug overdose deaths in the United States for the past two decades.

1069. In 2016 there were 349 opioid-related overdose deaths in New Mexico. This equals a rate of 17.5 deaths per 100,000 persons in 2016, much higher than the national rate of 13.3 deaths per 100,000 persons that same year.

1070. Across the state, New Mexico families and communities have faced heartbreaking tragedies that cannot be adequately conveyed by the overdose statistics, and have faced them all too often.

1071. Moreover, overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone, the antidote to opioid overdose.

1072. Injury and illness in New Mexico further extends beyond even overdoses and emergency response. According to the CDC, an increase in Hepatitis C in the United States is directly tied to intravenous injection of opioids.

1073. The deceptive marketing, overprescribing, and oversupply of opioids also had a significant detrimental impact on children in New Mexico. Young children have access to opioids, nearly all of which were prescribed or supplied to adults in their household, and children

have themselves been injured or killed. Children of parents addicted to opiates, described as the “invisible victims of the epidemic” are flooding the child protection system.

1074. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome (“NAS,” also known as neonatal opioid withdrawal syndrome, or “NOWS”). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

1075. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

1076. As a result of the impacts described above, and others, New Mexico local governments have incurred substantial expense to address the opioid epidemic created by



Defendants' misconduct. Local governments have funded, for example, medication-assisted treatment, residential treatment, recovery housing, detoxification programs, naloxone education, and prevention efforts, and have provided increased fire, and emergency services to cope with the opioid epidemic.

1077. The costs also include expenses associated with increased drug crimes, including costs for prosecutors, jails, adult probation, addiction treatment and alternative adult corrections providers, indigent defense, common pleas and/or drug court operations, juvenile court operations, and juvenile probation and detention. Local governments have also faced increased costs from non-drug offenses, such as burglary, elder abuse, or domestic violence, that also are related to opioid use. In addition to confronting rising numbers of inmates, local jails have also shouldered additional costs and burdens from opioid-addicted inmates, including providing services related to opioid detoxification and preventing suicides believed to be related to opioid withdrawal.

1078. New Mexico communities continue to evolve new strategies for fighting this epidemic. The needs, however, far outpace the available funding.

#### **H. Facts Specific to Colfax County**

1079. Plaintiff Colfax County has been deeply affected by the opioid crisis.

1080. The opioid crisis has reshaped daily reality for Plaintiff's Communities in numerous ways, including but not limited to increased and intensified emergency medical responses to overdoses; increased drug-related offenses affecting law enforcement, jails, and courts; enormous resources spent on community and social programs to treat those with opioid use disorders; higher workers' compensation costs for prescription opioids and opioid-related claims; and ultimately prevalent opioid abuse throughout the County, including in public places.

1081. While the County has committed substantial resources to address the crisis, the opioid epidemic is nowhere near contained. Fully addressing the crisis requires that those responsible for it pay for their conduct and to abate the nuisance and harms they have created in the County.

**1. The Opioid Epidemic Has Impacted Plaintiff's Community**

1082. In addition, the opioid crisis has evolved, and now heroin, fentanyl, and carfentanil use is the latest evolution in the opioid crisis in the County. As noted above, fentanyl and carfentanil are incredibly lethal. Adding to the danger, in some instances fentanyl has been made to look exactly like oxycodone tablets.

1083. Some of Plaintiff's Communities' most vulnerable residents have also become victims of the epidemic as children currently in foster care in Plaintiff's Communities continue to increase. This is directly related to the opioid epidemic, as parents struggling with opioid addiction may end up unable to care for their children, leading to children being removed from the home.

1084. Additionally, in the past several years there has been a significant increase in babies born addicted to opioids. These infants spend their first months of life suffering from withdrawal, a condition known as "Neonatal Abstinence Syndrome" (NAS). These children often need years of long-term care and monitoring due to NAS.

1085. Opioid related stories describe a public health crisis of epidemic proportions in Plaintiff's Communities. As a practical and financial matter, the County has been saddled with an enormous economic burden. Nearly every department in the County is affected by the opioid crisis caused by Defendants in some manner.

1086. Whatever the precise cost, there is no doubt that as a direct result of Defendants' aggressive marketing scheme and distribution of prescription opioids, the County has suffered

significant and ongoing harms—harms that will continue well into the future. Each day that Defendants continue to evade responsibility for the epidemic they caused, the County must continue allocating its resources to address it.

**2. Defendants Actively Promoted Opioids in Plaintiff's Communities and Were Aware of the Excessive Prescribing Practices That Followed**

1087. Sales representatives targeted their opioid promotion at health care providers in Plaintiff's Communities. They communicated the misrepresentations discussed in this Complaint to doctors, nurses, and staff in the County. Sales representatives, including those active in Plaintiff's Communities, knew or should have known the potential consequences of pushing potent doses of opioids for chronic pain and other common indications.

1088. Although Plaintiff does not presently know the names of the Marketing Defendants' sales representatives active in Plaintiff's Communities, through discovery this information will become available. Sales representatives' call notes, for example, will identify the strategies Marketing Defendants deployed specifically within Plaintiff's Communities and some of the specific misrepresentations they made.

1089. Defendants were fully aware of doctors and clinics whose prescribing activities were questionable. Yet, upon information and belief, Defendants did nothing to stop pills mills from operating, and to the contrary encouraged their activities by sending sales representatives to the pill mills and continuing to supply excessive quantities of opioids.

**3. Plaintiff's Communities Have Borne and Will Continue to Bear Substantial Costs as a Direct Result of Defendants' Misconduct**

1090. Plaintiff's Communities have been working to confront to the epidemic caused by Defendants' reckless promotion and distribution of prescription opioids, and the County allocates significant resources to respond to the crisis through nearly every department. The services and

programs offered by various departments and divisions in the County strain the County's annual budget.

1091. The County is responsible for the planning, funding, and monitoring of public mental health and alcohol and other drug addiction services delivered to the residents of Plaintiff's Communities. The County spends enormous sums for treatment programs, a large percentage of which is devoted to treating individuals with opioid-use disorder or dependence with programs for addiction treatment and recovery services, including residential treatment, intensive outpatient, prevention, detoxification, housing, employment, and education.

1092. Emergency Management Services (EMS) have also been hit hard by the crisis. EMS provides essential emergency medical and life-saving services within the County. Any time residents of Plaintiff's Communities call 9-1-1 for an emergency, they use the EMS system which partners with fire departments, paramedic agencies, EMS dispatch centers, and hospitals. EMS is at the front line of the opioid crisis, as they are the first on-scene responders to overdoses, deaths, and injuries related to opioid abuse. EMS incurs costs in dealing with the opioid crisis both in terms of responding to these emergencies and in training and preparing for them.

1093. The County's criminal justice system is also affected by the opioid crisis. The Sheriff's Department has dealt with an increasing number of opioid-related crimes, jails must spend additional amounts housing inmates involved in opioid-related crimes and providing opioid related services to inmates, and County's court system is saddled with a rising case load related to opioid abuse. Officers and deputies also are equipped with naloxone, and the County has incurred costs to ensure this life-saving drug is available to its deputies.

**I. No Federal Agency Action, Including The FDA, Can Provide The Relief Colfax County Seeks Here**

1094. The injuries Colfax County has suffered and will continue to suffer cannot be addressed by agency or regulatory action. There are no rules the FDA could make or actions the agency could take that would provide Colfax County the relief it seeks in this litigation.

1095. Even if prescription opioids were entirely banned today or only used for the intended purpose, thousands of Colfax County residents, and millions of Americans, would remain addicted to opioids, and overdoses will continue to claim lives. The County will respond to related medical emergencies and administer naloxone. The Sheriff's Office will spend extraordinary resources combatting illegal opioid sales, and the Colfax County courts will remain burdened with opioid-related crimes. Social services and public health efforts will be stretched thin.

1096. Regulatory action would do nothing to compensate the County for the money and resources it has already expended addressing the impacts of the opioid epidemic and the resources it will need in the future. Only this litigation has the ability to provide the County with the relief it seeks.

1097. Furthermore, the costs Colfax County has incurred in responding to the homeless crises and in rendering public services described above are recoverable pursuant to the causes of actions raised by the County. Defendants' misconduct alleged herein is not a series of isolated incidents, but instead the result of a sophisticated and complex marketing scheme over the course of more than twenty years that has caused a substantial and long-term burden on the municipal services provided by the County. In addition, the public nuisance created by Defendants and the County's requested relief in seeking abatement further compels Defendants to reimburse and

compensate Colfax County for substantial costs they have spent addressing the crisis caused by Defendants.

**J. The Defendants Conspired To Engage In The Wrongful Conduct  
Complained Of Herein and Intended To Benefit Both Independently and  
Jointly From Their Conspiracy**

**1. Conspiracy Among Marketing Defendants**

1098. The Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

1099. This interconnected and interrelated network relied on the Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants intended to mislead consumers and medical providers of the appropriate uses, risks, and safety of opioids.

1100. The Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of

time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

1101. The Marketing Defendants knew that none of these propositions is true and that there was no evidence to support them.

1102. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, health care providers, and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

1103. What is particularly remarkable about the Marketing Defendants' effort is the seamless method in which the Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Marketing Defendants effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

1104. The Marketing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

1105. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants.

1106. The most unnerving tactic utilized by the Marketing Defendants' network, was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased

and disinterested experts in the field, scientific method, and an unfounded theory or proposition would, or should, never gain traction.

1107. Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants were able to create a false consensus through their materials and references.

1108. An illustrative example of the Marketing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were *not* given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

1109. Nonetheless, Marketing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids in connection with taking opioids despite its obvious shortcomings. Marketing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

1110. Marketing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers that opioids were not a concern. The enormous impact of Marketing Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the



one-paragraph 1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy...

By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

## **2. Conspiracy Among All Defendants**

1111. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balance, to their collective advantage. Defendants agreed among themselves to increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

1112. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

1113. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below, including, for example, membership in the Healthcare Distribution Alliance.

1114. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants’ agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other’s compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants’ facilities.

1115. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA’s attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

1116. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had not basis for refusing to increase or decrease production quotas due to diversion.

1117. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

**K. Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses**

**1. Continuing Conduct.**

1118. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

1119. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

**2. Equitable Estoppel and Fraudulent Concealment**

1120. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

1121. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

1122. As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines,

informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers, and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Marketing Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

1123. Defendants also concealed from Plaintiff the existence of Plaintiff's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers, and the public, including Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

1124. Plaintiff did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on jurisdiction, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

1125. The Marketing Defendants’ campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff’s Community deceived the medical community, consumers, the State, and Plaintiff’s Community.

1126. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio Ordered the transactional ARCOS data be produced, over Defendants’ strenuous objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had not yet been produced, the Plaintiff *could not identify* the potential defendants in this litigation, and further held that such information was “critical”:

This means Plaintiffs still do not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Wal-Mart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). . . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation . . . . Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiffs’ claims, but also to the Court’s understanding of the width and depth of this litigation.

Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

1127. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff’s Community. Plaintiff and Plaintiff’s Community did not know and did not have the means to know the truth, due to Defendants’ actions and omissions.

1128. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

**L. Facts Pertaining to Punitive Damages**

1129. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

1130. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

1131. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large-scale economic loss to communities and government liabilities across the country.

1132. Defendants’ actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious and reckless disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Marketing Defendants’ fraudulent wrongdoing was done with a particularly gross and conscious disregard.

**1. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions**

1133. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings, and prosecutions. These governmental and regulatory actions included:

**a. FDA Warnings to Janssen Failed to Deter Janssen’s Misleading Promotion of Duragesic**

1134. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of “homemade” promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.” The March 30, 2000 letter detailed numerous ways in which Janssen’s marketing was misleading.

1135. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.” The September 2, 2004 letter detailed a series of unsubstantiated, false, or misleading claims.

1136. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been “examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch” and noted the possibility “that patients and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

**b. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses**

1137. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.

1138. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

**c. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora**

1139. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned:



“Fentora should not be used to treat any type of short-term pain.” Indeed, FDA specifically denied Cephalon’s application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

1140. Flagrantly disregarding the FDA’s refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora (“Warning Letter”). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden “the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case.” It further criticized Cephalon’s other direct Fentora advertisements because they did not disclose the risks associated with the drug.

1141. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled “An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate).” Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: “It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain.”

**d. A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin**

1142. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate,

misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

1143. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions - eight times what the gun lobby spent during that period.

**2. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion**

1144. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

1145. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

1146. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."

1147. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

- e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro, and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health’s Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and
- h. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

1148. McKesson’s deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 McKesson MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.”

1149. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause substantial harm.

1150. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA. McKesson's 2017 agreement with DEA documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

1151. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the \$150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

1152. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

DAVID SCHILLER: If they stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.

\* \* \*

They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.

[INTERVIEWER:] And they had none.

DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?<sup>325</sup>

1153. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

- a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";
- b. "[d]ocumentation evidencing new customer due diligence was incomplete";
- c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and
- d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's

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<sup>325</sup> Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), <https://www.cbsnews.com/news/whistleblowers-deaattorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/>.

compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

1154. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."

1155. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

1156. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

1157. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

1158. The New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and yet that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

1159. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).



1160. As all of the governmental actions against the Marketing Defendants and against all the Defendants shows, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

## **II. FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS (“RICO”) ACT**

### **A. The Opioid Marketing Enterprise**

#### **1. The Common Purpose and Scheme of the Opioid Marketing Enterprise**

1161. Knowing that their products were highly addictive, ineffective, and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants<sup>326</sup> formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

1162. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants formed an association-in-fact enterprise (the “Opioid Marketing Enterprise”) with the “Front Groups” and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise’s common purpose. The RICO Marketing Defendants’ substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.<sup>327</sup>

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<sup>326</sup> The RICO Marketing Defendants referred to in this section are those named in the First Claim for Relief under 28 U.S.C. § 1964(c), including Cephalon, Janssen, and Endo.

<sup>327</sup> *Fueling an Epidemic*, *supra* note 125.

1163. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants named “pseudoaddiction”; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

1164. The scheme devised, implemented, and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants’ drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise’s scheme, including through the unbranded promotion and marketing network as described above.

1165. There was regular communication between the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail

in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

1166. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits

1167. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' financial support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's

unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

1168. As public scrutiny and media coverage focused on how opioids ravaged communities throughout the United States, the Front Groups and KOLS did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

1169. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

1170. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC guidelines. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guidelines which represented "an important step - and perhaps the first major step from the federal government - toward limiting opioid prescriptions for chronic pain."

1171. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines.”

1172. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”

1173. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as “neutral” and more “scientific” than the RICO Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

1174. The impact of the Opioid Marketing Enterprise’s scheme is still in place - *i.e.*, the opioids continue to be prescribed and used for chronic pain throughout the area of Colfax County, and the epidemic continues to injure Plaintiff, and consume the resources of Plaintiff’s health care and law enforcement systems.

1175. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the KOLs are each willing participants in the Opioid Marketing Enterprise, share a common purpose and interest in the object of the scheme, and function within a structure designed to effectuate the Enterprise’s purpose.

## **2. The Conduct of the Opioid Marketing Enterprise violated Civil RICO**

1176. From approximately the late 1990s to the present, each of the Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the

operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. Creating and providing a body of deceptive, misleading, and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating and providing a body of deceptive, misleading, and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- c. Creating and providing a body of deceptive, misleading, and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- d. Creating and providing a body of deceptive, misleading, and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- e. Selecting, cultivating, promoting, and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;
- f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- g. Paying KOLs to serve as consultants or on the RICO Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
- h. Selecting, cultivating, promoting, creating, and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

- i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;
- l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;
- o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;
- p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and
- q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

1177. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups. The RICO Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States, including in and around Plaintiff's geographical area. The Front Groups and KOLS in the

Opioid Marketing Enterprise were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

1178. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;
- b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

1179. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."<sup>328</sup> "By aligning medical culture with industry goals in this way, many of the

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<sup>328</sup> *Fueling an Epidemic*, *supra* note 125, p. 1.



groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic.”<sup>329</sup>

1180. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants’ drugs that were consistent with the Marketing Defendants’ messages themselves;
- b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

1181. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants’ sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

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<sup>329</sup> *Id.* 2.

**3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use**

1182. As discussed in detail above, the RICO Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which appeared to be independent, but were not, transmitted the RICO Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

1183. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

1184. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

**4. Pattern of Racketeering Activity**

1185. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketing activity as described herein.

1186. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute

and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the RICO Marketing Defendants' misrepresentations.

1187. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud New Mexico consumers, the State, and other intended victims.

1188. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

1189. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain, to, prescribers, regulators, and the public, including Plaintiff, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

1190. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

- a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;
- b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally
- d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;
- e. E-mails, telephone, and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;
- f. Communications between the RICO Marketing Defendants, Front Groups, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities - the wrongful proceeds of the scheme.

1191. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

1192. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the Plaintiff: (a) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

1193. The RICO Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

1194. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

1195. The RICO Marketing Defendants’ predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff’s business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

**B. The Opioid Supply Chain Enterprise**

1196. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to “a categorical denial of any criminal behavior or intent.”<sup>330</sup> Defendants’ actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the “RICO Supply Chain Defendants” (the RICO Marketing Defendants and McKesson, Cardinal, and AmerisourceBergen) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

1197. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act (“CSA”). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good.

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<sup>330</sup> <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited, Apr. 21, 2018).

The CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an “anything goes” profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA’s closed system to conduct their own enterprise for evil.

1198. As “registrants” under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>331</sup> Critically, these Defendants’ responsibilities do not end with the products they manufacture or distribute – there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies’ opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

1199. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor’s illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead

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<sup>331</sup> 21 C.F.R. 1301.74(b).

to shrinking markets. The RICO Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

1200. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the RICO Supply Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure the largest possible financial return.

1201. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by fraudulently increasing the quotas set by the DEA that would



allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

1202. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

1203. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

- a. the quotas for prescription opioids should be increased;
- b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and
- e. they did not have the capability to identify suspicious orders of controlled substances.

1204. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress

to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”<sup>332</sup>

1205. The CSA and the Code of Federal Regulations require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

1206. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants’ applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

1207. The RICO Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through

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<sup>332</sup> See *HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, [https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9\\_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, [https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf\\_story.html](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html); Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->

virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

1208. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

1209. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

1210. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- c. Documents and communications that facilitated the manufacture, purchase, and sale of prescription opioids;
- d. RICO Supply Chain Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;
- f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

- g. Documents and communications related to the RICO Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of the RICO Supply Chain Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Marketing Defendants;
- k. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;
- l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;
- m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

1211. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
<b>Purdue</b>	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc.,	OxyContin	Oxycodone hydrochloride extended release	Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
	(3) The Purdue Frederick Company	MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic OxyContin	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. ( <i>wholly-owned subsidiary of Endo</i> )	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt PLC,	Exalgo	Hydromorphone hydrochloride	Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
	(2) Mallinckrodt LLC ( <i>wholly-owned subsidiary of Mallinckrodt PLC</i> )	Roxicodone	Oxycodone hydrochloride	Schedule II
<b>Actavis</b>	(1) Allergan Plc,	Kadian	Morphine Sulfate	Schedule II
	(2) Actavis LLC,	Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
	(3) Actavis Pharma, Inc.,	Generic Duragesic	Fentanyl	Schedule II
	(4) Actavis Plc,	Generic Opana	Oxymorphone hydrochloride	Schedule II
	(5) Actavis, Inc.,			
	(6) Watson Pharmaceuticals, Inc.,			
	Watson Pharma, Inc.			

1212. Each of the RICO Supply Chain Defendants identified manufactured, shipped, paid for, and received payment for the drugs identified above, throughout the United States.

1213. The RICO Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

1214. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

1215. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

1216. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

1217. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

1218. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

1219. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and

corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

1220. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1221. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

1222. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.<sup>333</sup>

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<sup>333</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.



1223. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Plaintiff's Community, and the Plaintiff. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens, or the Plaintiff. The RICO Supply Chain Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

1224. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

### **CLAIMS FOR RELIEF**

#### **FIRST CLAIM FOR RELIEF**

#### **Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Marketing Enterprise (Against All Marketing Defendants)**

1225. Plaintiff repeats, re-alleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein.

1226. The RICO Marketing Defendants – through the use of “Front Groups” that appeared to be independent of the RICO Marketing Defendants; through the dissemination of publications that supported the RICO Marketing Defendants’ scheme; through continuing medical education (“CME”) programs controlled and/or funded by the RICO Marketing Defendants; by the hiring and deployment of so-called “key opinion leaders,” (“KOLs”) who were paid by the RICO Marketing Defendants to promote their message; and through the

“detailing” activities of the RICO Marketing Defendants’ sales forces – conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through racketeering activities, the Opioid Marketing Enterprise sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

1227. The Opioid Marketing Enterprise alleged above, is an association-in-fact enterprise that consists of the RICO Marketing Defendants (Purdue Cephalon, Janssen, and Endo); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

1228. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise’s common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order to increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

1229. Specifically, the RICO Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

1230. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants false messages.

1231. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence their peers' medical practice by promoting the Marketing Defendant's false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the RICO Marketing Defendants' role in the enterprise and the enterprise's existence.

1232. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid

Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

1233. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and each of the Front Groups and KOLs; and (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

1234. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

1235. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to

increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

1236. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Marketing Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephones, and the Internet to transmit mailings and wires in interstate or foreign commerce.

1237. The RICO Marketing Defendants’ predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

1238. Indeed, as summarized herein, the RICO Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements,

electronic transmissions, and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

1239. Because the RICO Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiff have described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to New Mexico consumers, prescribers, regulators, and Plaintiff, and how those acts were in furtherance of the scheme.

1240. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including New Mexico consumers, prescribers, regulators, and Plaintiff. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

1241. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

1242. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

1243. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive New Mexico consumers, prescribers, regulators, and the Plaintiff. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including New Mexico consumers, prescribers, regulators, and the Plaintiff. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

1244. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

1245. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The

predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1246. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

1247. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in their business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially, and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not unexpected, unforeseen or independent.<sup>334</sup> Rather, as Plaintiff alleges, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.<sup>335</sup> Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

1248. It was foreseeable and expected that the RICO Marketing Defendants creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities

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<sup>334</sup> *Traveler's Property Casualty Company of America v. Actavis, Inc.*, 22 Cal. Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

<sup>335</sup> *Id.*



to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.<sup>336</sup>

1249. Specifically, the RICO Marketing Defendants' creation of, and then participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme has injured Plaintiff in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

- a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
- b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
- f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of

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<sup>336</sup> *Id.*

opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

- i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's community;
- l. Costs associated with extensive clean-up of public parks, spaces, and facilities of needles and other debris and detritus of opioid addiction;
- m. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- n. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

1250. Plaintiff's injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial, and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic the RICO Marketing Defendants created through their Opioid Marketing Enterprise, Plaintiff would not have lost money or property.

1251. Plaintiff is the most directly harmed entity and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

1252. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions, and programs; forfeiture as deemed proper by the

Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:

- a. Actual damages and treble damages, including pre-suit and post-judgment interest;
- b. An order enjoining any further violations of RICO;
- c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;
- d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;
- e. An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use, except as specifically approved by the FDA;
- f. An order enjoining any future marketing of opioids through non-branded marketing including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;
- g. An order enjoining any future marketing to vulnerable populations, including but not limited to, persons over the age of fifty-five, anyone under the age of twenty-one, and veterans;
- h. An order compelling the Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) pseudoaddiction is really addiction, not a sign of undertreated addiction; (4) withdrawal from opioids is not easily managed; (5) increasing opioid dosing presents significant risks, including addiction and overdose; (6) long term use of opioids has no demonstrated improvement of uncton; (8) use of time-released opioids does not prevent addiction; (9) abuse-deterrent formulations do not prevent opioid abuse; and (10) that manufacturers and distributors have duties under the CSA to monitor, identify, investigate, report and halt suspicious orders and diversion but failed to do so;
- i. An order enjoining any future lobbying or legislative efforts regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;

- j. An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research, or studies concerning the health risks or benefits of opioid use;
  - k. An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacturer, marketing, distribution, diversion, prescription, or use of opioids;
  - l. An order establishing a National Foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the Defendants in an amount to be determined by the Court;
  - m. An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious orders or diversion of opioids;
  - n. An order requiring all Defendants to publicly disclose all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity, or association regarding suspicious orders for or the diversion of opioids;
  - o. An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Marketing and Supply Chain Enterprises, including any interest in property associated with the Marketing and Supply Chain Enterprises;
  - p. Dissolution and/or reorganization of any trade industry organization, Front Group, or any other entity or association associated with the Marketing and Supply Chain Enterprises identified in this Complaint, as the Court sees fit;
  - q. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;
  - r. Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association, or enterprise named in the Complaint regarding the manufacture or distribution of opioids;
  - s. Forfeiture as deemed appropriate by the Court; and
1253. Attorney's fees and all costs and expenses of suit.

**SECOND CLAIM FOR RELIEF**

**Violation of RICO, 18 U.S.C. § 1961 *et seq.* – Opioid Supply Chain Enterprise  
(Against All Supply Chain Defendants– “RICO Supply Chain Defendants”)**

1254. Plaintiff repeats, re-alleges, and incorporates by reference each and every allegation set forth above as if fully set forth herein.

1255. At all relevant times, the RICO Supply Chain Defendants were and are “persons” under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, “a legal or beneficial interest in property.”

1256. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

1257. The RICO Supply Chain Defendants were members of the Healthcare Distribution Alliance (the “HDA”).<sup>337</sup> Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

1258. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the

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<sup>337</sup> Health Distribution Alliance, *History*, Health Distribution Alliance, (last accessed on September 15, 2017), <https://www.healthcaredistribution.org/about/hda-history>.

RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

1259. The RICO Supply Chain Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

1260. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Supply Chain Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

1261. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering

activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1262. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

1263. Each of the RICO Supply Chain Defendants is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

1264. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Supply Chain Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

- c. Controlled Substance Violations: The RICO Supply Chain Defendants who are Distributor Defendants violated 21 U.S.C. § 843 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

1265. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

1266. The RICO Supply Chain Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

1267. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

1268. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

1269. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

1270. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts



also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1271. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

1272. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.

1273. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

1274. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

1275. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

1276. It was foreseeable to the RICO Supply Chain Defendants that Plaintiff would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion

of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA intended to prevent.

1277. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

1278. The RICO Supply Chain Defendants’ violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The RICO Supply Chain Defendants’ pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially, and foreseeably cause an opioid epidemic. Plaintiff was injured by the RICO Supply Chain Defendants’ pattern of racketeering activity and the opioid epidemic that they created.

1279. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.<sup>338</sup> Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.<sup>339</sup>

1280. The RICO Supply Chain Defendants’ predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Plaintiff in the form of substantial

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<sup>338</sup> *Traveler’s Property Casualty Company of America v. Actavis, Inc.*, 22 Cal. Rptr. 3d 5, 19 (Cal. Ct. App. 2017).

<sup>339</sup> *City of Everett v. Purdue Pharma L.P.*, 2017 WL 4236062, \*6 (W.D. Wash. Sept. 25, 2017).

losses of money and property that logically, directly, and foreseeably arise from the opioid-addiction epidemic.

1281. Specifically, Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

- a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
- b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
- f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;
- h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- i. Costs associated with increased burden on Plaintiff's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's community;
- l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

1282. Plaintiff's injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial, and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by Defendants' conduct, Plaintiff would not have lost money or property.

1283. Plaintiff's injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

1284. Plaintiff is most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

1285. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions, and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, and all of the relief sought in the First Claim for Relief, as the Court deems just and applicable.

**THIRD CLAIM FOR RELIEF**  
**Violations of the New Mexico Unfair Trade Practices Act**  
**(Against All Defendants)**

1286. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

1287. The New Mexico Unfair Trade Practices Act, N.M.S.A. § 57-12-1, et seq. (“UTPA”) prohibits “unfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce.”

1288. During the relevant periods and as detailed further herein, the Marketing Defendants have each engaged in unconscionable, unfair and/or deceptive acts or practices in commerce in violation of the UTPA by actively promoting and marketing the use of opioids for indications not federally approved, and circulating false and misleading information concerning opioids’ safety and efficacy. The Marketing Defendants’ large-scale acts of deception were successful, as these acts and practices were likely to mislead customers acting reasonably under the circumstances both to grossly underestimate the risks associated with the Marketing Defendants’ opioid products as well as overestimate the products’ efficacy.

1289. The Marketing Defendants have also each engaged in unconscionable, unfair and/or deceptive acts or practices in commerce in violation of the UTPA by downplaying or omitting the risk of addiction arising from the use of their prescription opioids and omitting the lack of clinical evidence to substantiate their claims of efficacy and safety.

1290. Each of the Distributor Defendants has engaged in unconscionable and unfair acts or practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of “registrants” by the federal CSA, 21 C.F.R. § 1301.74(b). The CSA defines “registrant” as any person who is registered pursuant to 21 U.S.C. § 823. 21 C.F.R. § 1300.02(b). Section 823(a)-(b) requires manufacturers and distributors of Schedule II controlled substances to register.

1291. All Defendants' unconscionable, unfair, or deceptive acts or practices in violation of the UTPA offend public policy, are immoral, unethical, oppressive, and unscrupulous, as well as malicious, wanton and manifesting of ill will, and they caused substantial injury to the Plaintiff. Plaintiff risks irreparable injury as a result of all Defendants' acts, misrepresentations, and omissions in violation of the UTPA, and these violations present a continuing risk to Plaintiff, as well as to the general public. Increased risk of future harm due to the widespread addiction caused by Defendants' acts and practices and widespread manipulation of the medical profession.

1292. All Defendants' acts and practices in violation of the UTPA offend public policy, are immoral, unethical, oppressive, or unscrupulous, as well as malicious, wanton and manifesting ill will; caused and continue to cause substantial injury to Plaintiff and its inhabitants; and put Plaintiff at increased risk of future harm.

1293. As a direct and proximate result of all Defendants' violations of the UTPA, Plaintiff has suffered and continues to suffer losses constituting injury-in-fact. Plaintiff is entitled, and does hereby seek, to recover its actual damages and its attorneys' fees and costs.

1294. Plaintiff has been seriously aggrieved by all Defendants' violations of the UTPA and is therefore entitled to, and does hereby, seek an order declaring all Defendants' acts and practices and unlawful under and in violation of the UTPA and enjoining all Defendants' unfair, unconscionable, and/or deceptive acts or practices, and awarding attorneys' fees, costs and any other just and proper relief available under the UTPA.

**FOURTH CLAIM FOR RELIEF**  
**Common Law Absolute Public Nuisance**  
**(Against All Defendants)**

1295. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

1296. Defendants created and maintained a public nuisance which proximately caused injury to Plaintiff.

1297. A public nuisance is an unreasonable interference with a right common to the general public.

1298. Defendants have created and maintained a public nuisance by marketing, distributing, dispensing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiff's community, and Plaintiff and the residents of Plaintiff's community have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

1299. The public nuisance is an absolute public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others.

1300. Defendants have created and maintained an absolute public nuisance through their ongoing conduct of marketing, distributing, dispensing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiff's community, flooded Plaintiff's community with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiff and the residents of Plaintiff's community.

1301. Defendants know, and have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiff and Plaintiff's communities.

1302. Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of Plaintiff and Plaintiff's community. *See* Restatement (Second) of Torts § 821B.

1303. The interference is unreasonable because Defendants' nuisance-creating conduct: (a) Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience; (b) At all relevant times was and is proscribed by state and federal laws and regulations; and/or (c) Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

1304. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes: (a) The creation and fostering of an illegal, secondary market for prescription opioids; (b) Easy access to prescription opioids by children and teenagers; (c) A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths; (d) Infants being born dependent on opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts; (e) Employers have lost the value of productive and healthy employees; and (f) Increased costs and expenses for Plaintiff relating to



healthcare services, law enforcement, the criminal justice system, social services, and education systems.

1305. Defendants intentionally and unreasonably and/or unlawfully deceptively marketed and pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death, and injuries to the residents of Plaintiff's community, a higher level of fear, discomfort, and inconvenience to the residents of Plaintiff's community, and direct costs to Plaintiff and Plaintiff's community.

1306. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to Plaintiff.

1307. A violation of any rule or law controlling the sale and/or distribution of a drug of abuse in Plaintiff's community constitutes an absolute public nuisance.

1308. In the sale distribution, and dispensation of opioids into Plaintiff's community, Defendants violated federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74.

1309. Defendants' unlawful nuisance-creating conduct includes violating federal and State statutes and regulations, including the controlled substances laws, by (a) Distributing, dispensing, dispensing, and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market; (b) Distributing, dispensing, and selling without maintaining effective controls against the diversion of opioids; (c) Choosing not to effectively monitor for suspicious orders; (d) Choosing not to investigate suspicious orders; (e) Choosing not to report suspicious orders; (f) Choosing not to stop or suspend shipments of suspicious orders; (g)

Distributing, dispensing, and selling opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills;” (h) Defendants’ intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

- a. Distributing, dispensing, and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and dispensing, opioids without maintaining effective controls against the diversion of opioids;
- c. Choosing not to effectively monitor for suspicious orders;
- d. Choosing not to investigate suspicious orders;
- e. Choosing not to report suspicious orders;
- f. Choosing not to stop or suspend shipments of suspicious orders; and
- g. Distributing, dispensing, and selling opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills.”

1310. Defendants intentionally and unreasonably distributed, dispensed, and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

1311. Defendants are in the business of distributing, and/or dispensing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because inter alia these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

1312. Indeed, opioids are akin to medical-grade heroin. Defendants’ wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiff—exactly as would be expected when medical-grade

heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

1313. Defendants had control over their conduct in Plaintiff's community and that conduct has had an adverse effect on rights common to the general public. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

1314. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to Plaintiff described herein.

1315. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

1316. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiff's community and the harm inflicted outweighs any offsetting benefit.

1317. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

1318. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

1319. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

1320. The nuisance created by Defendants' conduct is abatable.

1321. Defendants' misconduct alleged in this case is ongoing and persistent.

1322. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

1323. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

1324. Plaintiff seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

1325. Plaintiff has suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than the State's citizens at large. These are harms that can only be suffered by Plaintiff.

1326. Plaintiff is asserting their own rights and interests and Plaintiff's claims are not based upon or derivative of the rights of others.

1327. The tortious conduct of each Defendant was a substantial factor in creating the absolute public nuisance.

1328. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiff.

1329. Plaintiff has suffered an indivisible injury as a result of the tortious conduct of Defendants.

1330. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

1331. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre and post-judgment interest.

**FIFTH CLAIM FOR RELIEF**  
**Public Nuisance**  
**(Against All Defendants)**

1332. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

1333. Each Defendant's conduct, both individually and collectively, in creating and then maintaining the opioid crises constitutes a public nuisance. The conduct of each Defendant involves a significant interference with the public health, the public safety, the public peace, and the public comfort. Each Defendant's conduct giving rise to the opioid crisis is of a continuing nature and has produced a permanent or long-lasting effect that, as each Defendant knows or has reason to know, has a significant effect on the entire community.

1334. Each Defendant's interference with the public health, the public safety, the public peace, and the public resulted significant harm to Plaintiff. The significant harm that each

Manufacturer Defendant has caused the community and the public by its conduct in creating and then maintaining the opioid crisis for its own individual profit is substantially offensive and intolerable.

1335. Each Defendant intentionally caused the public nuisance complained of herein. The conduct of each Defendant, either individually or collectively, was a substantial factor in producing and then maintaining the opioid crisis that is a significant interference with the public health, the public safety, the public peace, and the public comfort.

1336. Each Defendant acted either knowing, or was substantially certain, that its false, deceptive, and misleading information and statements regarding the dangers, addictive nature and abuse potential of their opioid products would result in the public nuisance and significant harm complained of herein.

1337. Each Defendant acted either knowing, or was substantially certain, that its failure to maintain effective controls over the distribution of prescription opioids, including by oversupplying prescription opioids and by fulfilling and failing to identify or report suspicious orders, would result in the public nuisance and significant harm complained of herein.

1338. Each Defendant was also negligent as each engaged in the conduct complained of herein to create an unreasonable risk of the public nuisance complained of herein, and then failed to abate the public nuisance they created. Moreover, each Defendant's negligent conduct, both individually and collectively, was a cause of the public nuisance complained of herein.

1339. Each Defendant's conduct in causing the public nuisance complained of herein was unreasonable and the gravity of the harm caused far outweighs any utility of the Defendant's conduct.

1340. Each Defendant's conduct damaged, and continues to damage Plaintiff in an amount to be determined at trial.

1341. Plaintiff seeks monetary and injunctive relief to halt the threat of future harm.

**SIXTH CLAIM FOR RELIEF**

**Negligence  
(Against All Defendants)**

1342. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

1343. Defendants have a duty to exercise reasonable care in the distribution of prescription opioids.

1344. Reasonable care includes the duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to maintain effective controls over the distribution of prescription opioids, including to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market, and to identify, report, and refuse to fill suspicious orders.

1345. Defendants, acting individually, together, and in concert with others, were negligent both generally and in not utilizing their specialized and sophisticated knowledge, information, skill, and understanding to maintain effective controls over the distribution of prescription opioids, including to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market, and to identify, report, and refuse to fill suspicious orders.

1346. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the improper or unlawful acts of third parties.

1347. As a proximate result of the Defendants breach of their duties of care, Defendants and its agents damaged and continues to damage Plaintiff in an amount to be determined at trial.

**SEVENTH CLAIM FOR RELIEF**

**Unjust Enrichment  
(Against All Defendants)**

1348. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

1349. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Plaintiff's Community, including from opioids foreseeably and deliberately diverted within and into Plaintiff's Community.

1350. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

1351. Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

1352. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

1353. These expenditures have helped sustain Defendants' businesses.

1354. Plaintiff has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

1355. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

1356. Plaintiff has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with



a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Marketing Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

1357. Defendants have unjustly retained benefits to the detriment of Plaintiff, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

1358. Defendants' misconduct alleged in this case is ongoing and persistent.

1359. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

1360. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

1361. Plaintiff seeks an order compelling Defendants to disgorge all unjust enrichment to Plaintiff; and awarding such other, further, and different relief as this Honorable Court may deem just.

### **EIGHTH CLAIM FOR RELIEF**

#### **Fraud (Against All Defendants)**

1362. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

1363. Defendants, individually and acting through their employees and agents, and in concert with each other, misrepresented material facts with regards to the use of opioids to treat chronic pain through various means including but not limited to:

- a. Creating and/ or disseminating advertisements, scientific studies, CMEs, and patient and prescriber education materials that contained false, misleading, and untrue statements concerning the ability of opioids to improve function long-term;
- b. Creating and/or disseminating advertisements, scientific studies, CMEs, and patient and prescriber education materials that contained false, misleading, and untrue statements concerning the ability of opioids to improve quality of life while concealing contrary data;
- c. Creating and/or disseminating advertisements, scientific studies, CMEs, and patient and prescriber education materials that contained false, misleading, and untrue statements concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain, including known rates of abuse and addiction and lack of validation for long-term efficacy;
- d. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction, even for high-risk patients;
- e. Disseminating misleading statements concealing the true risk of addiction in the elderly;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an imbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Falsely claiming that withdrawal is simply managed; and
- h. Misrepresenting that increased doses of opioids pose no significant additional risks.

1364. Defendants' false representations and concealments were made with the intent to deceive the Plaintiff; as well as consumers in the Plaintiff's Community who used or paid for opioids for chronic pain; physicians who prescribed opioids to consumers to treat chronic pain; and payors, who purchased, or covered the purchase of, opioids for chronic pain.

1365. Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic pain.

1366. Defendants knew that, with prolonged use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.

1367. Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use in managed settings where the risk of addiction and other adverse outcomes was significantly minimized.

1368. Despite the foregoing knowledge, in order to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches, and did so through misrepresentations including those listed above.

1369. Defendants' misrepresentations saturated the market, were promulgated in part by third parties positioned as experts, and extended to almost every available source of information including prescribing guidelines, CMEs, patient educational materials, and journal publications.

1370. Plaintiff did reasonably rely on these false representations made by Defendants and third parties in their control.

1371. But for these false representations and concealments of material fact, Plaintiff would not have purchased or covered the purchase of opioids for chronic pain. But for these false representations, there would not have been a massive opioid addiction and overdose epidemic that has strained the Plaintiff's budgets.

1372. Defendants' conduct damaged and continues to damage the Plaintiff in an amount to be determined at trial.

**NINTH CLAIM FOR RELIEF**

**Civil Conspiracy  
(Against All Defendants)**

1373. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

1374. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids into New Mexico and Plaintiff's Community.

1375. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into New Mexico and Plaintiff's Community.

1376. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

1377. The Marketing Defendants further unlawfully marketed opioids in New Mexico and Plaintiff's Community in furtherance of that conspiracy.

1378. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in Plaintiff's Counts for violations of RICO. Such allegations are specifically incorporated herein.

1379. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

1380. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

1381. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

1382. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

1383. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

1384. Defendants' misconduct alleged in this case is ongoing and persistent.

1385. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

1386. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

1387. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and

all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre-and post-judgment interest.

**PRAYER FOR RELIEF**

1388. Plaintiff respectfully requests that this Court enter an order of judgment granting all relief requested in this complaint, and/or allowed at law or in equity, including:

- a. abatement of the nuisance;
- b. actual damages;
- c. treble or multiple damages and civil penalties as allowed by statute;
- d. punitive damages;
- e. exemplary damages;
- f. disgorgement of unjust enrichment;
- g. equitable and injunctive relief in the form of Court-enforced corrective action, programs, and communications;
- h. forfeiture, disgorgement, restitution and/or divestiture of proceeds and assets;
- i. attorneys' fees;
- j. costs and expenses of suit;
- k. pre- and post-judgment interest; and
- l. such other and further relief as this Court deems appropriate.

**Jury Demand**

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury on all issues so triable under the law.

Dated: March 24, 2021.

**DURHAM, PITTARD & SPALDING, LLP**

By: /s/Justin R. Kaufman

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